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IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO EASTERN DIVISION

- - -

IN RE: NATIONAL : HON. DAN A. POLSTER

PRESCRIPTION OPIATE

LITIGATION :

:

APPLIES TO ALL CASES : NO.

: 1:17-MD-2804

- HIGHLY CONFIDENTIAL -

SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

JANUARY 16, 2019

- - -

Videotaped sworn deposition of
TRACEY L. NORTON, taken pursuant to
notice, was held at BEST WESTERN LEHIGH
VALLEY HOTEL & CONFERENCE CENTER, 300
Gateway Drive, Bethlehem, Pennsylvania,
beginning at 8:51 a.m., on the
abovedate, before Margaret M. Reihl, a
Registered Professional Reporter,
Certified Shorthand Reporter, Certified
Realtime Reporter, and Notary Public.

_ _ _

GOLKOW LITIGATION SERVICES 877.370.3377 ph | 917.591.5672 fax deps@golkow.com

Page 2	Page 4
SEEGER WEISS LLP SEEGER WEISS LLP BY: DAVID BUCHANAN, ESQUIRE ELINA RAKHLIN, ESQUIRE SCOTT SIEGEL, PARALEGAL 55 Challenger Road Ridgefiled Park, New Jersey 07660 (212) 584-7732 erakhlin@seegerweiss.com Representing the Plaintiffs MORGAN & MORGAN BY: JAMES YOUNG, ESQUIRE RAYMOND TAMAYO, ESQUIRE (telephonic) TERESA DuBUISSON-MAI, ESQUIRE (telephonic) RENFE COOK, ESQUIRE (telephonic) SHAWKURA SHAW, ESQUIRE (telephonic) 10 RENFE COOK, ESQUIRE (telephonic) SHAWKURA SHAW, ESQUIRE (telephonic) 11 JENNIFER WILLIAMS, ESQUIRE (telephonic) 12 JANIFER WILLIAMS, ESQUIRE (telephonic) 13 JENNIFER WILLIAMS, ESQUIRE (telephonic) 14 MCCARTER & SIGLISH BY: AMY M. VANNI, ESQUIRE 16 1600 Market Street Suite 3900 17 Philadelphia, Pennsylvania 19103 (215) 979-3848 avanni@mccarter.com - AND - 19 BY: HAYLEY J. REESE, ESQUIRE 405 N. King Street, 8th Floor Wilmington, Delaware 19801 (302) 984-6308 1 hrees@mccarter.com Representing the Defendant Endo and the witness	1 APPEARANCES: (cont'd) 2 JONES DAY BY: TAYLOR A. GOODSPEED, ESQUIRE 3 555 California Street, 26th Floor San Francisco, California 94104-1500 4 (415) 626-3939 tgoodspeed@jonesday.com 5 Representing the Defendant Walmart 6 BARNES & THORNBURG BY: WILLIAM J. LEEDER, III, ESQUIRE 8 171 Monroe Avenue N.W. Suite 1000 9 Grand Rapids, Michigan 49503-2694 bleeder@btlaw.com 10 Representing the Defendant H.D. Smith 11 ALSO PRESENT: 12 13 Sandra Di Iorio, Litigation Counsel Endo 14 Kevin Frank, Videographer 15 Bradley Smith, Trial Technician 16 17 18 19 20 21 22 23 24
Page 3	Page 5
A P P E A R A N C E S: (cont'd) KIRKLAND & ELLIS LLP BY: JENNIFER G LEVY, ESQUIRE 655 Fifteenth Street, N W Washington, D C 20005 (202) 879-5211 jennifer levy@kirkland com Representing the Defendant Allergan REED SMITH LLP BY: LOUIS W SCHACK, ESQUIRE Three Logan Square 1717 Arch Street, Suite 3100 Philadelphia, Pennsylvania 19103 (215) 851-8280 Ischack@reedsmith com Representing the Defendant AmerisourceBergen FOLEY & LARDNER LLP BY: KATY E KOSKI, ESQUIRE 111 Huntington Avenue Boston, Massachusetts 02199-7610 (617) 342-4000 Koski@foley com Representing the Defendant Anda MORGAN LEWIS & BOCKIUS LLP BY: MARTHA A LEIBELL, ESQUIRE 200 South Biscayne Boulevard Suite 5300 Miami, Florida 33131-2339 (305) 415-3387 martha leibell@morganlewis com Representing the Defendant Teva	TELEPHONIC APPEARANCES: TUCKER ELLIS LLP BY: SAVANNAH M FOX, ESQUIRE 950 Main Avenue, Suite 1100 Cleveland, Ohio 44113 (216) 696-3950 savannah fox@tuckerellis com Representing the Defendants Janssen and J&J WILLIAMS & CONNOLLY LLP BY: JOSEPH S BUSHUR, ESQUIRE 725 Twelfth Street, N W Washington, D C 20005 (202) 434-5013 jousher@wc com Representing the Defendant, Cardinal Health ALLEGAERT BERGER & VOGEL LLP BY: LUCY N ONYEFORO, ESQUIRE 111 Broadway, 20th Floor New York, New York 10006 (212) 616-7050 callegaert@abv com Representing the Defendant, Rochester Drug Co-operative, Inc ALSTON & BIRD LLP BY: JENNY A HERGENROTHER, ESQUIRE 1201 West Peachtree Street NW Atlanta, Georgia 30309 (404) 881-4977 20 jenny hergenrother@alston com Representing the Defendant Noramco

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                                                                                                  NO.
                                                                                                           DESCRIPTION
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        WITNESS
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                                                                                                  Par-
        TRACEY L NORTON
                                                                                                   Norton-12 E-mail dated 10/7/13
               By Mr Buchanan
                                             13
                                                                                                         with attachment produced natively, Subject,
                                                                                            4
               By Mr Young
                                           496
 4
                                                                                            5
                     EXHIBITS
 5
                                                                                                         [PAR_OPIOID_MDL_0000018920] 269
 6
        NO
                 DESCRIPTION
                                                PAGE
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        Par-
                                                                                                  Norton-13 E-mails dated 3/13/13,
        Norton-1 Resume
                                             13
                                                                                            7
                                                                                                         Subject, FW: Slide Deck
 8
                                                                                            8
                                                                                                         for This Morning's Meeting,
        Par-
                                                                                                         produced natively
 9
        Norton-2 Charts, Par Total Pills
                                                                                                         [PAR_OPIOID_MDL_0000365381
               Shipped 2008-2015
10
               [E1157 1 and 1157 2]
                                                                                                  Norton-14 E-mail dated 11/7/13.
11
                                                                                           11
                                                                                                         Subject SOMS Update
        Norton-3 E-mail dated 10/15/14, with
                                                                                                         with attached presentation
produced natively
12
               attachments
                                                                                           12
               [HDS_MDL_00404792 through
                                                                                                         [PAR_ OPIOID MDL_ 0000376972] 333
13
               4798]
                                                                                           13
        Par-
14
                                                                                                  Norton-15 E-mail string, top one dated 2/9/13, Subject,
        Norton-4 E-mail dated 9/30/14
                                                                                           14
15
               with attachment
                                                                                                         DEA Compliance Initiatives
                                                                                           15
               [PAR_OPIOID_MDL-0001059825
                                                                                                         Presentation, attachments
[PAR_OPIOID_MDL_0000034190
and 0001424664 to 4667] 347
16
               through 9827]
                                                                                           16
        Norton-5 E-mail string, top one
                                                                                           17
18
               dated 2/27/14, Subject
               FW: Bellco-Qualitest SOMS
                                                                                           18
                                                                                                   Norton-16 E-mail dated 2/9/13, Subject
                                                                                                         DEA Compliance Initiatives
Presentation, with attachment
19
               [ABDCMDL00337067 to 7073]
                                                     138
                                                                                           19
20
                                                                                                         [PAR_OPIOID_MDL_0000034190
        Norton-6 E-mail string, top one
                                                                                                         to 4215]
                                                                                           20
21
               dated 7/16/13, Subject,
                                                                                           21
               FW: SOMS Customer Letter
                                                                                                   Norton-17 E-mail dated 1/4/13, Subject
               & Sales Rep Talking Points
22
                                                                                           22
                                                                                                         Today's Meeting, with attachments, natively produced
               [PAR_ OPIOID MDL_ 0000372485
               to 2492]
                                                                                           23
                                                                                                         [PAR OPIOID MDL 0000363469] 385
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                EXHIBITS (cont'd)
                                                                                                           EXHIBITS (cont'd)
                                                                                                          DESCRIPTION
 3
       Par-
                                                                                            3
       Norton-7 Effective Controls Against
                                                                                                  Par-
 4
             Diversion of Controlled
                                                                                            4
                                                                                                  Norton-18 E-mails dated 11/16/11,
             Substances, Meeting with
                                                                                                        Subject, RE: DEA Inspection
             Vintage Pharmaceuticals
                                                                                                        Wrap-Up in Charlotte
            March 6, 2013
[PAR_OPIOID_MDL_0002016179
                                                                                                        (11/15/2011)
 6
                                                                                                       [PAR_ OPIOID MDL_ 0000390035
                                                                                            6
             to 6588]
                                                                                                        to 0037]
 7
 8
                                                                                                  Norton-19 E-mail string, top one
       Norton-8 E-mail string, top
                                                                                            8
                                                                                                        dated 9/13/12, Subject
Re: DEA Revokes Two CVS
             one dated 3/7/13,
             Subject, FW: Charts from
                                                                                                        Retailers' Ability To Sell
             DEA Meeting, with
             attachments
[ENDO-OPIOID MDL-02975958
10
                                                                                           10
                                                                                                        Controlled Substance
                                                                                                        [PAR_OPI01D_MDL_0000397090
                                                                                                       to 7092]
       Norton-9 E-mail string, top one
dated 11/12/15, Subject
                                                                                                  Norton-20 E-mail dated 9/4/08,
13
                                                                                           13
                                                                                                       Subject, Qualitest 08-2008 doc
             FW: Information captured
                                                                                                        with attachment
14
             from DEA Meeting
                                                                                           14
                                                                                                        [PAR_OPIOID_MDL_0000076009
             [PAR_OPI01D_MDL_0000006058
                                                                                                        to 6011]
15
                                                                                           15
             to 6059]
16
       Norton-10 E-mail string, top one
dated 6/23/17, Subject
                                                                                           16
                                                                                                  Norton-21 E-mail string, top one dated 10/21/14, Subject,
17
             letter you ask for,
                                                                                           17
                                                                                                        RE: EXTERNAL: FW: Due
18
             with attached memorandum [PAR_OPI01D_MDL_000021619
                                                                                                       Diligence and Revised SOM [PAR_OPIOID_MDL_0000001708
                                                                                           18
19
             and PAR_OPI01D_MDL_0000216199
                                                                                                        to 17121
                                                                                           19
             to 6201]
                                  245
20
                                                                                           20
                                                                                                  Norton-22 Qualitest letter dated
21
       Norton-11 E-mail string, top one
             dated 11/12/15, Subject
                                                                                           21
                                                                                                       [PAR_OPIOID MDL_0000024197] 431
22
             FW: DEA meeting notes
                                                                                           22
                                                                                                  Norton-23 Qualitest letter dated
23
             [PAR_OPIOID MDL_0000006053
                                                                                           23
                                                                                                       [PAR_OPIOID MDL_0000024197] 444
             to 60571
24
                                                                                           24
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1 2	EXHIBITS (cont'd) NO DESCRIPTION PAGE	1	Congratulations, by the way?
3	Par-	2	A. Thank you.
4	Norton-24 E-mail dated 11/21/14, Subject, Secondary customers	3	Q. Have you ever been deposed
5	with attached letter [ENDO HSGAC 0015838 to 5840] 445	4	before?
6	Par-	5	A. I have not.
7	Norton-25 E-mail dated 5/26/16, Subject, FW: Minutes from	6	Q. Okay. It's a Q and A. I'm sure
8	the Anti-Diversion Working Group Meeting - 10/8/2013	7	you had a chance to meet with counsel before you
9	with attachment [PAR OPIOID MDL 0000009576	8	came in today. It's, you know, a little more
10	to 9579] 456	9	formal. Obviously, you see a videographer. You
	Par-	10	see a court reporter taking down everything that
11	Norton-26 DEA Compliance Trip Report 11/14/13	11	we say together. So it's going to be important
12	[PAR_OPIOID_MDL_0001252760	12	that I do my best to wait until you're done
13	•	13	answering to ask my questions and that you wait
14	Par- Norton-27 E-mail dated 10/28/14,	14	until my question is done to start answering.
15	Subject, BuzzeoPDMA 9th Regional DEA Seminar -	15	Fair?
	Agenda and Presentations	16	A. Absolutely.
16	with attachments [PAR_OPI01D_MDL_0000016438	17	Q. Okay. The way this goes is
17 18	to 6639] 480 Par-	18	there's going to be a written transcript, so if
19	Norton-28 Project Initiation Form (PIF) [HDS Hernandez 00037 and	19	you don't understand the question, but you
	[HDS_Hemandez_0003/ and HDS_MDL_00302301] 508	20	answer it anyway, the record is going to reflect
20	Par-	21	that you understood the question. So if there's
21	Norton-29 H D Smith Meeting Minutes 9/7/16	22	1
22	[H0S_MDL_00294884 to 4886] 528		confusion in my questions, and there might be,
23	Par- Norton-30 E-mail dated 2/3/15, Subject 539	23	I'm prone to confusing questions at times, just
24	CSOMP Analysis, with attachment [HDS_MDL_00407087 to 7088]	24	ask me to clarify, and I'll do my best to make
	Page 11		Page 13
1	THE VIDEOGRAPHER: Good morning,	1	it better for you, okay?
2	we are now on the record. Today's date	2	A. Okay, thank you.
3	is January 16, 2019. The time is	3	Q. Ms. Norton, I see that you are a
3 4		3 4	
	approximately 8:51 a m. This is the		person who over the course of your 25-plus years
4	approximately 8:51 a m. This is the videotaped deposition of Tracey	4	person who over the course of your 25-plus years in the pharmaceutical industry have had a focus
4 5	approximately 8:51 a m. This is the videotaped deposition of Tracey Hernandez in the National Prescription	4 5	person who over the course of your 25-plus years
4 5 6 7	approximately 8:51 a m. This is the videotaped deposition of Tracey Hernandez in the National Prescription Opiate Litigation. All counsel and	4 5 6 7	person who over the course of your 25-plus years in the pharmaceutical industry have had a focus on compliance and DEA compliance in particular, is that fair?
4 5 6	approximately 8:51 a m. This is the videotaped deposition of Tracey Hernandez in the National Prescription Opiate Litigation. All counsel and parties present will be noted on the	4 5 6	person who over the course of your 25-plus years in the pharmaceutical industry have had a focus on compliance and DEA compliance in particular, is that fair? A. Yes, that's correct.
4 5 6 7 8 9	approximately 8:51 a m. This is the videotaped deposition of Tracey Hernandez in the National Prescription Opiate Litigation. All counsel and parties present will be noted on the stenographic record.	4 5 6 7 8 9	person who over the course of your 25-plus years in the pharmaceutical industry have had a focus on compliance and DEA compliance in particular, is that fair? A. Yes, that's correct. MR. BUCHANAN: I've been handed
4 5 6 7 8 9	approximately 8:51 a m. This is the videotaped deposition of Tracey Hernandez in the National Prescription Opiate Litigation. All counsel and parties present will be noted on the stenographic record. Will the court reporter please	4 5 6 7 8 9	person who over the course of your 25-plus years in the pharmaceutical industry have had a focus on compliance and DEA compliance in particular, is that fair? A. Yes, that's correct. MR. BUCHANAN: I've been handed an updated copy of your resume we've
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	approximately 8:51 a m. This is the videotaped deposition of Tracey Hernandez in the National Prescription Opiate Litigation. All counsel and parties present will be noted on the stenographic record. Will the court reporter please swear in the witness. TRACEY L. NORTON, having been duly sworn as a witness, was examined and testified as follows: BY MR. BUCHANAN Q. Good morning, ma'am. I think we just said this is the deposition of Tracey Hernandez, but I see from your updated resume that you're now Tracey Norton. A. Correct. Q. Please forgive me if at times I	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	person who over the course of your 25-plus years in the pharmaceutical industry have had a focus on compliance and DEA compliance in particular, is that fair? A. Yes, that's correct. MR. BUCHANAN: I've been handed an updated copy of your resume we've marked as Exhibit 1 to your deposition. (Document marked for identification as Par-Norton Deposition Exhibit No. 1) MR. BUCHANAN: Pass a copy back. Do you have one already, Counsel? MS. VANNI: I do, thank you. MR. BUCHANAN: There's one for you all to share and one for my colleague at the small table. BY MR. BUCHANAN

	Page 14		Page 16
1	Q. You prepared it on your own?	1	Q. And home just so we're clear,
2	A. Yes.	2	home is Bethlehem, Pennsylvania?
3	Q. Okay. And you didn't have any	3	A. Bethlehem.
4	input from counsel into what to say and what not	4	Q. Looks like where you finished up
5	to say?	5	in Novartis, and let's just get the dates on
6	MR. VANNI: Object to form.	6	that, you were there from '87 to 2002? I say
7	THE WITNESS: No.	7	Novartis, Ciba-Geigy.
8	BY MR. BUCHANAN:	8	A. Correct.
9	Q. When I say you prepared it on	9	Q. '87 to 2002, you finished up in
10	your own, maybe somebody looked it over for you	10	DEA, PDMA or in that department as a manager,
11	to help you	11	fair?
12	A. Years ago someone at like a	12	A. Yes.
13	resume service helped with some of it, but it's	13	Q. And what is DEA?
14	been modified several times by me since then.	14	A. DEA is Drug Enforcement
15	Q. Okay. Okay. They helped you get	15	Administration.
16	the framework together, but you own it?	16	Q. And PDMA?
17	A. Correct.	17	A. Prescription Drug Marketing Act.
18	Q. You are comfortable with it, fair	18	Q. And you had some role for
19	enough?	19	regulatory compliance in that group?
20	A. Correct.	20	MS. VANNI: Object to form.
21	Q. I want to focus with you	21	THE WITNESS: Yes.
22	principally on your time while you were with the	22	BY MR. BUCHANAN:
23	Endo entities, I guess Qualitest and Endo,	23	Q. I see that you acted as a
24	depending on the timeline and maybe Par.	24	consultant I'm looking at the second bullet
	depending on the timerine and mayor ran.		consultant. Thi looking at the second bullet
	Page 15		Page 17
1	You left in 2014, though,	1	point "acted as a consultant to the division
2	correct?	2	for issues associated with these regulations."
3	A. Correct. I've never worked for	3	Would these be DEA regulations?
4	Par.	4	A. Correct.
5	Q. So we'll focus on Endo/Qualitest,	5	Q. Okay. "Quota, ARCOS,
6	okay?		
		6	import/export, 222 forms, in-transit
7	I understand, though, before you	7	import/export, 222 forms, in-transit losses/thefts, returns/disposals, et cetera,"
8	I understand, though, before you joined Endo, you worked in the pharmaceutical		losses/thefts, returns/disposals, et cetera,"
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8 9	joined Endo, you worked in the pharmaceutical industries?	7 8	losses/thefts, returns/disposals, et cetera," correct? A. Yes.
8	joined Endo, you worked in the pharmaceutical industries? A. Yes, that's correct.	7 8 9	losses/thefts, returns/disposals, et cetera," correct? A. Yes. Q. Okay. And you've got other
8 9 10	joined Endo, you worked in the pharmaceutical industries?	7 8 9 10	losses/thefts, returns/disposals, et cetera," correct? A. Yes. Q. Okay. And you've got other details on here as we go down, I think, to the
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	Page 18		Page 20
1	ARCOS; is that right?	1	recall exactly when it transitioned from
2	A. Yes.	2	Ciba-Geigy to Novartis. So when I was
3	Q. That's a system that	3	the DEA PDMA manager, I had that
4 .	manufacturers and the DEA communicate back and	4	responsibility.
5	forth about sales?	5	BY MR. BUCHANAN:
6	MS. VANNI: Objection.	6	Q. Okay. So SOM was something that
7	THE WITNESS: And other things.	7	you were engaged with maybe more tangentially
8	BY MR. BUCHANAN:	8	while you were at Ciba-Geigy/Novartis, fair?
9	Q. I'm sorry. Yeah. Could be the	9	MS. VANNI: Objection.
10	acquisition of controlled substances?	10	THE WITNESS: I'm sorry.
11	A. Yes.	11	BY MR. BUCHANAN:
12	Q. The disposition of controlled	12	Q. I'll let you describe it. I'm
13	substances?	13	not trying to mischaracterize it in any way. It
14	A. It's all transactions or most	14	didn't sound like you had primary responsibility
15	transactions with certain controlled substances.	15	for Novartis' SOM system, fair?
16	Q. Okay. And or SOMs, what is	16	MS. VANNI: Objection.
17	SOMs?	17	THE WITNESS: It was Novartis'
18	A. Suspicious order monitoring.	18	SOM system was in place prior to my
19	Q. And that term may come up today	19	coming, and I maintained it and may have
20	more than ten times, so how do you use that	20	modified along the way, so yes.
21	acronym?	21	BY MR. BUCHANAN:
22	A. SOM.	22	Q. Okay. And when we talk about
23	Q. You do? Okay. So you supervised	23	SOMs, we're talking about a system for reporting
24	the development of controlled drug reporting	24	orders, orders of concern, suspicious orders to
	Page 19		Page 21
	1490 13		
1	systems such as we talked about ARCOS briefly	1	Page 21 the DEA related to controlled substances fair?
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2	and then SOM.	2	the DEA related to controlled substances, fair? MS. VANNI: Objection.
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1	Page 22		Page 24
1	BY MR. BUCHANAN:	1	to the company and to work to work to improve
2	Q. And we'll circle back on that	2	or to end ultimately to comply with those
3	more specifically as we go through today, but to	3	regulations.
4	start with, I mean, the statute has been the	4	Q. And some of the things that you
5	same, correct?	5	consider obviously as a compliance manager are
6	A. Yes.	6	the regulations themselves, right?
7	Q. And a manufacturer and	7	A. Yes.
8	distributor has to maintain a manufacturer	8	Q. You consider how the DEA is
9	and distributor of controlled substances has to	9	applying or interpreting or enforcing those
10	maintain effective controls against diversion,	10	regulations?
11	correct?	11	MS. VANNI: Objection.
12	MS. VANNI: Objection.	12	THE WITNESS: Yes. And the
13	THE WITNESS: Registrants have to	13	reason I say yes is because different
14	maintain.	14	local offices sometimes apply them
15	BY MR. BUCHANAN:	15	differently, but, yes, overall.
16	Q. Fair enough. And a registrant	16	BY MR. BUCHANAN:
17	who is a manufacturer, a registrant that is a	17	Q. You go to industry conferences
18	distributor has to maintain effective controls	18	and you hear what others have to say about what
19	against diversion, correct?	19	they're doing to and how they're interpreting
20	A. Yes.	20	the regulations to ensure compliance?
21	Q. And I take it, then, during your	21	MS. VANNI: Objection.
22	time with Novartis Novartis was a registrant?	22	THE WITNESS: Yes, to a certain
23	A. Correct.	23	extent within confidentiality.
24	Q. Okay. There are also obligations	24	BY MR. BUCHANAN:
	Page 22		Davis 25
	Page 23		Page 25
1	under the regulations that have been passed by	1	Q. And we'll probably have a chance
2	the DEA with regard to the monitoring and	2	to talk about some of that today. You've been
3	reporting of suspicious orders, correct?	3	on various committees, antidiversion working
4	MS. VANNI: Objection.	4	groups, various distributor associations,
5	THE WITNESS: Yes, there's a	5	various manufacturer associations where you've
6	regulation.	6	gone and attended and received input as to I'll
7	BY MR. BUCHANAN:	7	say antidiversion and SOM practices, fair?
8	Q. Okay. And in your field, I've	8	MS. VANNI: Objection.
9	seen at various times that you've been characterized as a, quote, DEA compliance	9	THE WITNESS: Well, antidiversion, yes, yes.
10		10	
11	manager; would that be fair?	11 12	BY MR. BUCHANAN:
12 13	A. Yes. Q. And when you is compliance a	13	Q. In fact, you've presented at them, correct?
	•		
14	field?	14 15	A. Yes.
15 16	A. Yes. Q. Could you describe generally what	16	Q. So that's one of the ways in
16 17	Q. Could you describe generally what compliance is, as a field?	17	which those in the industry get information about, if you will, state-of-the-art compliance,
18	A. Well, there's a lot of different	18	state-of-the-art SOM practices, state-of-the-art
19	types of compliance. Are you referring	19	antidiversion practices, true?
20	specifically to DEA compliance?	20	MS. VANNI: Objection.
∠ ∪	Q. I am.	21	THE WITNESS: Yes and no. A lot
21	γ. ι αιιι.	1	
21	Δ Okay The goal of individuals in	1 22	
22	A. Okay. The goal of individuals in	22	of things aren't shared because of the
	A. Okay. The goal of individuals in those positions is to become familiar with the DEA regulations and to apply those regulations	22 23 24	confidentiality, so I always say I want to hear it from the horse's mouth, I

	Page 26		Page 28
1	want to hear it from DEA. I do take	1	issues while you were at Watson with regard to
2	into consideration, but ultimately any	2	Watson's DEA compliance?
3	changes I implement would be based on	3	MS. VANNI: Objection.
4 .	things that I would hear from the DEA.	4	THE WITNESS: Not that I can
	Y MR. BUCHANAN:	5	recall.
6	Q. And as a manufacturer, as a	6	BY MR. BUCHANAN:
	istributor of controlled substances, there's	7	Q. Did you ever have any issues
	lso just the general responsibility to ensure	8	while you were at Watson with regard to Anda's
	nat your product isn't getting to places where	9	compliance?
	's not supposed to get, right?	10	MS. VANNI: Objection.
11	MS. VANNI: Objection.	11	THE WITNESS: I was not I
12	THE WITNESS: Yes.	12	didn't have responsibility for Anda. I
	Y MR. BUCHANAN:	13	was consulted on occasion and did help
14	Q. And you recognize that?	14	out at certain points, but it was not my
15	MS. VANNI: Objection.	15	ultimate responsibility.
16	THE WITNESS: It's part of the	16	BY MS. DICKINSON:
17	regulation.	17	Q. I mean, they got called in to the
	Y MR. BUCHANAN:	18	DEA for some issues, right?
19	Q. And part of your obligation as	19	A. Yes.
	ne manufacturer distributor?	20	Q. Were you the one responsible for
21	MS. VANNI: Objection.	21	the oversight of that problem before it was
22	THE WITNESS: To follow the	22	brought to the DEA?
23	regulations.	23	MS. KOSKI: Object to form.
	Y MR. BUCHANAN:	24	THE WITNESS: No, I had no
	T HAG BEETH WHY.		
	Page 27		Page 29
1	Q. Okay. Let's look, then, at where	1	responsibility for Anda up until that
2 y e	ou went after after Novartis. You went to	2	point.
-	Vatson; is that right?	3	BY MR. BUCHANAN:
4	A. Yes, that's correct.	4	Q. Okay. So as I understand the
5	Q. And if I understand correctly	5	timeline, you're at Watson from 2002 to 2009.
6 d	uring your time at Watson, there was an	6	You finish as the director of controlled
	equisition of another company Anda?	7	substances compliance. Within that function,
8	A. Anda, yes.	8	you had responsibility for suspicious order
9	Q. Is that how it's pronounced Anda,	9	monitoring for Watson, correct?
10 it	's not ANDA?	10	A. Yes.
11	A. Yeah. ANDA would refer more to	11	Q. And then Watson at a point in
12 a	n FDA acronym.	12	time acquired Anda, correct?
13	Q. I thought that was why they did	13	A. Yes.
14 th	nat. But okay. It's Anda. Thank you.	14	Q. Anda got called in by the DEA for
15	So Watson acquired Anda and	15	some violations, fair?
	uring your tenure at Watson?	16	MS. KOSKI: Object to form.
17	A. Yes.	17	THE WITNESS: Not for violations,
18	Q. Okay. I just need to draw a	18	no.
	istinction between the companies.	19	BY MR. BUCHANAN:
20	With regard to Watson, did you	20	Q. Okay. They had a sit-down with
	ave a role in responsibility for DEA	21	the DEA?
	ompliance?	22	MS. KOSKI: Object to form.
23	A. Yes.	23	THE WITNESS: It was part of the
24	Q. Okay. Did you ever have any	24	distributor initiative.

	Page 30		Page 32
1	BY MR. BUCHANAN:	1	She was a Qualitest employee.
2	Q. And let's make sure we understand	2	BY MR. BUCHANAN:
3	your role in that.	3	Q. Yeah, I'm thinking of you in the
4	Shortly after Watson purchased	4	Endo family of companies, Endo being Endo was
5	Anda, Anda was summoned to the DEA as a result	5	the owner of Qualitest?
6	of their lack of a robust SOM program, correct?	6	A. Endo was the owner, but there was
7	MS. KOSKI: Object to form.	7	a separate business from Qualitest, and I was
8	THE WITNESS: No, that's not	8	not not responsible for that business. I
9	correct. DEA DEA was had	9	handled just Qualitest really for the most part.
10	initiated what they termed a distributor	10	Q. Okay. All right, fair. So this
11	initiative, and they called all	11	is during your time at Qualitest, then, shortly
12	distributors at different times to the	12	before you left. And looks like about two
13	headquarters office to talk about sales	13	months before you left Qualitest in November
14	of their product.	14	of 2014; is that right?
15	BY MR. BUCHANAN:	15	A. Yes.
16	Q. Okay. So I'm not sure that we	16	Q. Okay. It's an e-mail between
17	can pin down the date, or at least in my	17	somebody in HR at H.D. Smith and yourself.
18	examination we won't be pinning down the date,	18	"Please call Tracey at the phone number at"
19	but at a point in time when you were at Watson,	19	blank. "She is expecting your call right now.
20	do you remember roughly when this was that you	20	Thanks for the last minute."
21	got called in with Anda to meet with the DEA?	21	There's two attachments. One is
22	MS. KOSKI: Object to form.	22	your resume.
23	THE WITNESS: I don't. I would	23	Do you see that?
24	assume closer to the time I left, but I	24	A. Yes.
	Page 31		Page 33
		1	~
1	don't know for sure.	1	Q. Another is a document entitled
1 2	don't know for sure. (Document marked for	1 2	
			Q. Another is a document entitled
2	(Document marked for	2	Q. Another is a document entitled "SOMs Experience"?
2	(Document marked for identification as Par-Norton Deposition	2 3	Q. Another is a document entitled "SOMs Experience"? A. Mm-hmm.
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	Page 34		Page 36
1	register notice or conversations if there were	1	Do you see that?
2	customers that were high-risk customers, right?	2	A. So the Federal Registers would
3	A. Yes.	3	be
4	Q. And that was something that was	4	Q. I'm sorry, I just need to make
5	reasonable to do at that time, to comply with	5	sure that you
6	your obligation as a manufacturer?	6	A. Yes, I see that.
7	MS. VANNI: Object to form.	7	Q. Okay. And if you're what
8	THE WITNESS: Yes, it was.	8	you're doing there is you're looking to external
9	BY MR. BUCHANAN:	9	sources, in this case, the Federal Register
10	Q. And so one of the things you were	10	notices or conversations with the DEA to
11	doing while at Ciba-Geigy or Novartis was, you	11	determine and to ensure that your customers are
12	know, monitoring customers to see if customers	12	not high risk, right?
13	were, in fact, high-risk customers, right?	13	MS. VANNI: Objection.
14	MS. VANNI: Objection.	14	THE WITNESS: Yes. If a customer
15	THE WITNESS: Monitoring	15	appeared in a Federal Register notice
16	customers for suspicious orders.	16	and had a license suspended or had
17	BY MR. BUCHANAN:	17	action taken against them, I would
18	Q. Right. Which you note here in	18	contact them to customer service to
19	your writing. And these are your words,	19	make sure that they weren't, in fact, a
20	correct?	20	customer that we were shipping to.
21	A. Yes.	21	BY MR. BUCHANAN:
22	Q. "If a customer was deemed a high	22	Q. Right. So when you became aware
23	risk and should be discontinued."	23	
23		24	that there were customers that were engaged in
24	Do you see that at the bottom?	24	problematic activities, you notified customer
	Page 35		Page 37
1	A. On Ciba-Geigy?	1	service so customer service ceases activity or
2	Q. Yes.	2	you got comfort that we weren't doing business
3	A. Yes.	3	with them or Ciba-Geigy wasn't doing business
4	Q. And so you understood, at least	4	with them?
		4	With them.
5	The state of the s	5	
5 6	during your time at Novartis and during your		MS. VANNI: Objection. THE WITNESS: Yes.
	The state of the s	5	MS. VANNI: Objection.
6	during your time at Novartis and during your time at Ciba-Geigy, that was one of the obligations of a manufacturer distributor?	5 6	MS. VANNI: Objection. THE WITNESS: Yes. BY MR. BUCHANAN:
6 7	during your time at Novartis and during your time at Ciba-Geigy, that was one of the obligations of a manufacturer distributor? MS. VANNI: Objection.	5 6 7	MS. VANNI: Objection. THE WITNESS: Yes. BY MR. BUCHANAN: Q. And for clarity, ma'am, what was
6 7 8 9	during your time at Novartis and during your time at Ciba-Geigy, that was one of the obligations of a manufacturer distributor? MS. VANNI: Objection. THE WITNESS: To notify for	5 6 7 8 9	MS. VANNI: Objection. THE WITNESS: Yes. BY MR. BUCHANAN: Q. And for clarity, ma'am, what was the period of time when you were working at
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Page 38 Page 40 1 1 Okay. And one of the ways that Yes. 2 2 you did that at that point in time was by Q. Okay. And those are your words 3 notifying customer service of high-risk 3 certainly in characterizing your experience at 4 customers, correct? 4 Watson with regard to Anda and that particular 5 MS. VANNI: Object to form. 5 DEA interaction, correct? 6 6 THE WITNESS: Yes. It was not a Yes. 7 requirement that I notify them, but, 7 And what you note after that, and Q. 8 obviously, I don't want to ship to 8 I think to -- well, I'll ask you this. What you 9 9 note after that was "I did not support Anda from someone who has a suspended license or 10 10 a DEA perspective, as they had come to Watson has issues. 11 BY MR. BUCHANAN: 11 with their own DEA person. However, I was asked 12 to be their DEA representative for the meeting 12 Whether it was a requirement or 13 not, that's what you did at that point in time 13 in HQ. I went with legal and the individual who 14 14 as part of you executing your role and function at the time was the president of Anda. DEA 15 in DEA compliance for Ciba-Geigy and Novartis, 15 presented and provided a binder, as they have 16 16 fair? done for most companies at this point. However, 17 17 in Anda's case, the DEA meeting was for cause, MS. VANNI: Objection. 18 18 and immediate action was required." THE WITNESS: Yes, always tried 19 to go above and beyond, yes. 19 Did I read that correctly? 20 20 BY MR. BUCHANAN: Yes. A. Q. Okay. And it was reasonable to 21 21 Q. Okay. So this particular meeting 22 do that, right? 22 with regard to Anda was different than the other 23 23 meetings that you were aware that were happening MS. VANNI: Objection. THE WITNESS: Mm-hmm. 24 24 in the industry at that point in time, correct? Page 39 Page 41 1 BY MR. BUCHANAN: 1 MS. KOSKI: Object to form. 2 2 THE WITNESS: It was -- I'm Q. Is that a yes? 3 A. Yes. 3 sorry, can you repeat that? 4 Okay. It looks like while you 4 BY MR. BUCHANAN: 5 were at Watson, you didn't have any interactions 5 Q. This particular meeting with 6 concerning the SOM program in terms of 6 regard to Anda was different than the other 7 7 deficiencies in your SOM program relevant to the meetings that you were aware of that were 8 Watson part of the business, fair? 8 happening between DEA and the industry at that 9 9 point in time, correct? A. 10 10 Then you note "However, Watson MS. KOSKI: Objection. O. purchased Anda." 11 11 THE WITNESS: It was the same 12 Do you see that in the middle of 12 type of meeting. It was a distributor 13 13 the page, the middle of the Watson page? initiative. They reviewed the same type 14 A. Yes. 14 of data. The individuals that we met It says "However, Watson 15 15 with presented it a little differently 16 16 purchased Anda and shortly afterward, Anda was than other meetings I had been at. 17 summoned to DEA a result of their lack of a 17 BY MR. BUCHANAN: 18 robust SOM program." 18 Q. Okay. This particular meeting as 19 Do you see that? 19 you characterized it in summarizing your SOM 20 20 experience at and Watson -- and, again, we're A. 21 Okay. And that was the reference 21 Q. referring at the meeting with DEA and Anda --22 I mentioned five, ten minutes ago with regard to 22 you characterize it as a meeting for cause, 23 why you went to see the DEA. 23 correct? 24 24 Do you see that, ma'am? I did characterize it that way.

	Page 42		Page 44
1	However, there was no DEA violation. There was	1	THE WITNESS: I actually don't
2	no action taken by DEA against Anda. It was a	2	know what they had. What was and I
3	meeting to share information, and that was also	3	also didn't know their customer base.
4	my first experience with a distributor.	4	Since I hadn't worked with them up to
5	Everything up to that point had been more on the	5	that point, I was told that I, you know,
6	manufacturing side, so to me at the time, it was	6	was not to handle Anda from a DEA
7	spun a little bit differently.	7	perspective, that was someone else's
8	Q. Okay. I understand that this	8	responsibility. So I was pulled into
9	meeting was different than prior meetings you	9	the meeting really without having any
10	had had kind of with your manufacturer hat on.	10	background on the company.
11	A. Right.	11	BY MR. BUCHANAN:
12	Q. But with regard to this meeting,	12	Q. Right. You are a DEA compliance
13	and you wrote this, to be clear, some five	13	person. Watson has just acquired Anda. There's
14	years, six years after the meeting, right?	14	a situation that has occurred that apparently is
15	A. Yes.	15	being seen as a serious situation because the
16	Q. Okay. And the way you	16	president as a company knew, correct?
17	characterized it with the benefit of hindsight	17	A. He was very concerned, yes.
18	and looking backward was a meeting for cause	18	Q. And Anda grabs you from the
19	with immediate action required, correct?	19	Watson side, please come and sit next to us in
20	A. Yes. I think you need to take	20	this meeting while we take the bullets we're
21	into context the purpose of the document,	21	going to take on this?
22	though. You know, I'm trying to get a job, so	22	MS. KOSKI: Object to form.
23	obviously I'm trying to make myself look very	23	THE WITNESS: They actually asked
24	good to this company and to kind of put forth	24	me to come because of my because I
2 1	good to this company and to kind of put forth		the to come occause of my occause i
	Page 43		Page 45
1	that, you know, this company needed me at this	1	knew the people that had called them to
2	time, and I stepped in and helped out and was	2	the meeting. I had interacted with them
3	able to resolve an issue, so	3	previously on multiple occasions and
4	Q. Well, yeah, and I suppose, you	4	they had had reached out to me. So I
5	know, thank you for, I would say, being candid	5	think they felt more comfortable that I
6	and reflecting the context in which this was	6	would, you know, have a good working
7	prepared, but you were also saying, weren't you,	7	relationship with them and would
8	that the problems that Anda had were not mine?	8	would help the meeting to go smoothly.
9	MS. KOSKI: Object to form.	9	BY MR. BUCHANAN:
10	THE WITNESS: They became mine.	10	Q. Okay. And so in that context,
11	BY MR. BUCHANAN:	11	how you characterized it at least for purposes
12	Q. Right. We could read this, and	12	of reflectively, looking back at that time, was
13	it says "Watson had no issues with DEA regarding	13	that they were summoned to the DEA as a result
14	their SOMs program during my seven-year tenure."	14	of their lack of a robust SOM program and that
15	A. Mm-hmm.	15	the DEA meeting was for cause and immediate
16	Q. "However, Watson purchased Anda	16	action was required, those were some reflections
17	and shortly afterward, Anda was summoned to DEA	17	that you noted on this particular meeting, fair,
18	as a result of their lack of a robust SOM	18	ma'am?
19	program."	19	A. That's what I noted in the
20	Did I read that correctly?	20	document, yes.
21	A. Yes.	21	Q. And then you said after that, you
22	Q. Was that true that they did not	22	worked with the president and "we reviewed
23	have a robust SOM program?	23	numerous customers and cut many"; is that right?
24	MS. KOSKI: Object to form.	24	A. Yes, probably too many.
	110. 1200H. Object to form.		11. 100, producty too many.

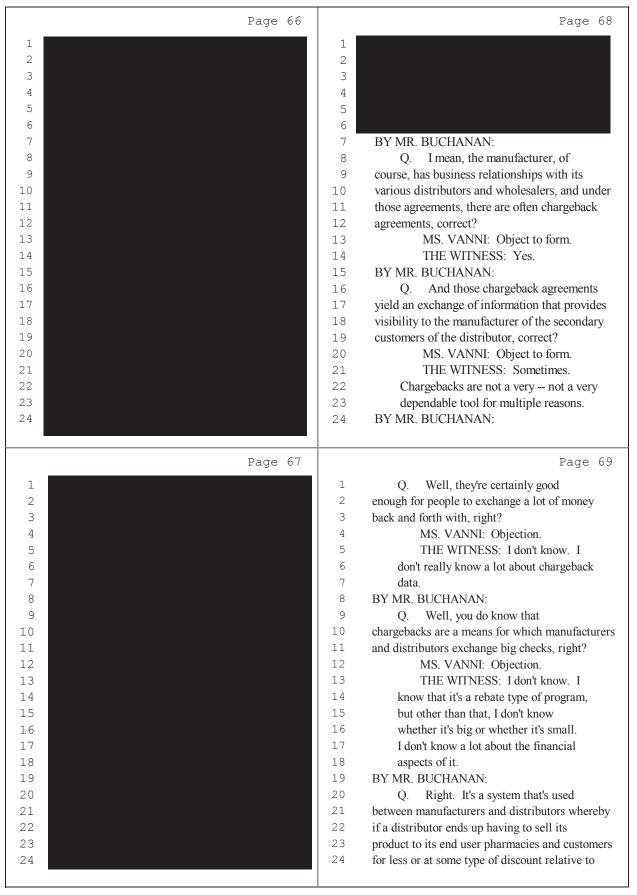
Page 48 Page 46 1 1 So during the time that you were responsibility for them, I don't really 2 at Watson -- and you left there when, ma'am? 2 know what they were doing. 3 A. 3 BY MR. BUCHANAN: 4 4 Q. So prior to 2009, during your Q. Well, we know they didn't have a 5 5 time with Watson in connection with your role robust SOM program, right? 6 6 and oversight of Anda, when you started to work MS. KOSKI: Object to form. 7 with the president to actually look at the 7 THE WITNESS: Well, that's 8 customers in a manner like you had looked at 8 opinion-based, to be honest. 9 9 customers at Novartis and Ciba-Geigy, you cut BY MR. BUCHANAN: 10 10 many customers, correct? Q. And certainly opinion-based four 11 MS. KOSKI: Object to form. 11 years ago, right? 12 THE WITNESS: It wasn't in the 12 MS. KOSKI: Object to form. 13 same manner and, again, because I didn't 13 THE WITNESS: Yes. 14 know their business, the president 14 BY MR. BUCHANAN: 15 15 really took it upon himself. At that Q. Nearer in time than today, right? 16 meeting, DEA had -- one of the 16 A. I'm sorry? 17 17 individuals at DEA had thrown out a Nearer in time to the events than O. 18 number as far as dosage forms, and they 18 today, correct? 19 said that they felt that a pharmacy 19 A. Yes. 20 20 should not receive more than this Q. And a program that certainly 21 amount, and that's what the president 21 necessitated immediate action, fair? 22 worked with. He really took it to the 22 MS. KOSKI: Object to form. 23 23 extreme and was very concerned about it BY MR. BUCHANAN: 24 and cut off a lot of customers as a 24 Q. That's what you wrote at a point Page 47 Page 49 1 1 result. in time nearer to today? 2 2 I think, unfortunately for Anda, A. Yes, that's what I wrote. 3 in doing that, the number was a -- kind 3 Q. And you said some other things 4 4 of an ad hoc number thrown out by DEA, that you implemented with them -- and this is 5 5 again, when the SOM program was back in at least before 2009, "Prior to my 6 6 developing. So they just cut based on leaving," you said you were "instrumental in 7 7 that number only, and they didn't look convincing Watson to start looking at drug 8 at the customer's business and whether 8 combinations, i.e., Holy Trinity and to begin 9 9 that business actually required more customer visits for the purpose of SOM which I 10 10 volume. believe they now contract out to a third party. 11 11 Did I read that correctly? So, you know, they took a very, 12 very aggressive approach and were very 12 Yes. A. 13 13 concerned about the information the DEA Q. So during the time that you were 14 had shared. 14 at Watson and I guess you were helping them to 15 further reshape their SOM program, is this 15 BY MR. BUCHANAN: 16 16 Watson/Anda or is this Watson? O. Right. 17 17 A. This is Watson. We can agree, certainly, that 18 prior to the point of time of that sit-down with 18 Q. So on the manufacturer side --19 the DEA, Anda had not been looking at customers 19 when we said Watson we're thinking manufacturer 20 in a manner that was looking for suspicious 20 and when we're thinking Anda you're thinking 21 21 more distributor; is that fair? orders, correct? 22 MS. KOSKI: Object to form. 22 A. Yes. 23 23 THE WITNESS: I can't really say With regard to Watson as a 24 that, again, because I didn't have 24 manufacturer back in 2009 they were starting to

Page 50 Page 52 1 implement customer visits but they were doing 1 correct? with a third party? 2 2 A. Again, not sure if that actually 3 A. They were -- I have that, I 3 came to fruition or not. 4 believe, they now contract out to a third party. 4 What you noted here --Q. 5 I don't know if they implemented that after I 5 It was something we talked about. A. 6 6 left. -- "prior to my leaving, I was instrumental" -- your words, correct, 7 Q. 7 Okay. 8 A. Watson was very -- very proactive 8 "instrumental"? 9 and it wasn't just based on my input, it was 9 A. Mm-hmm. 10 really a team effort and customer service was 10 Q. -- "in convincing Watson to start 11 also very proactive in -- we worked together to 11 looking at drug combinations, i.e., Holy 12 kind of go above and beyond. There was no 12 Trinity, and to begin customer visits for the requirement for Holy Trinity -- you know, to 13 13 purpose of SOM, which I believe they now look at Holy Trinity. There was no requirement 14 14 contract out to a third party." 15 for -- there were certain products that weren't 15 Did I read that correctly? controlled yet, but that we had heard there was 16 16 A. To start looking at beginning 17 an abuse potential that we added to the system, 17 customer visits, to start looking at. There's a 18 so a lot of good things that were added above 18 difference between implementing versus start 19 and beyond. 19 looking at. So doing research as to whether or 20 20 Well, there is a requirement to not they wanted to implement customer visits. 21 maintain effective controls against diversion, 21 There's a lot involved in implementing that. 22 true? 22 Q. The jury has your words, but the 23 A. Yes, within -- within the 23 words you wrote was, "I was instrumental in regulations which apply. When they're talking 24 24 convincing Watson" -- and you list two things, Page 51 Page 53 1 more about effective controls against diversion, 1 right? 2 2 you know, reporting suspicious orders, it's MS. VANNI: Object to form. 3 not -- it's not all-encompassing. It includes a 3 THE WITNESS: Mm-hmm. 4 security provision, accountability, 4 BY MR. BUCHANAN: 5 recordkeeping. 5 "I was instrumental in convincing 6 Q. Let's just separate the two so 6 Watson," and then you say the first one, "to 7 7 start looking at drug combinations," that is, we're not kind of fusing them together. 8 The statutory obligation for 8 Holy Trinity. That was the first item, correct? 9 9 manufacturers and distributors who are A. Yes. 10 10 registrants, thank you for that clarification, Q. Holy Trinity is what? 11 11 is to maintain effective controls against A. It's a combination of 12 diversion, fair? 12 hydrocodone, carisoprodol and alprazolam. 13 13 A. Is to make sure that you are In your field, and certainly in DEA compliance, you understood that the Holy 14 doing everything that you can to prevent your 14 15 product from being diverted into a list of 15 Trinity, those three drugs, were often abused in 16 channels. 16 combination, fair? 17 And one of the things that you 17 That's what I was told at A. 18 implemented or helped Watson implement during 18 conferences, yes. 19 19 your time there was expanding their And so as far back as at this 20 antidiversion controls to include looking at 20 point in time, sometime prior to 2009, when you 21 drug combinations like Holy Trinity. That was 21 were at Watson, you were instrumental in 22 one thing, correct? 22 convincing Watson to start looking at that drug 23 23 A. Yes. combination as a combination of abuse, fair? 24 24 To begin customer visits, A. Yes.

	Page 54		Page 56
1	Q. Okay. And then you said there	1	doing and had implemented was they were doing
2	was a second thing you were instrumental in,	2	license checks in connection with each order,
3	correct?	3	correct?
4	A. Mm-hmm.	4	A. Mm-hmm, yes.
5	Q. You were instrumental in	5	Q. It was something that they were
6	"convincing Watson to begin customer visits for	6	already doing before you got there, right?
7	the purpose of SOM, which I believe they now	7	A. Yes.
8	contract out to a third party."	8	Q. So if you were there from 2002 to
9	Did I read that correctly?	9	2009, they had already implemented as part of
10	A. Yes.	10	their order flow a license check every time
11	Q. All right. So that takes us	11	somebody placed an order to ensure that the
12	through your time at Watson. Actually, let's go	12	customer was permitted to receive the product,
13	up the page a little bit.	13	correct?
14	Characterizing some other things	14	A. Yes.
15	that Watson was doing on the manufacturing side,	15	Q. All right. That was actually
16	you list the way in which they handled SOM	16	something you implemented for Ciba-Geigy and
17	during the seven years you were there.	17	Novartis, right?
18	Do you see that?	18	A. Yes.
19	A. Mm-hmm.	19	Q. If we go up on the page
20	Q. We can start at the beginning.	20	A. Mm-hmm.
21	"Conducted audits as noted above, Watson already	21	Q it says "responsible for
22	utilized NTIS, but based on the requirements of	22	conducting internal audits of customer service."
23	several states, added the process for collecting	23	You talk about "to assure
24	customer state license information."	24	customer licensing was obtained and verified."
	Page 55		Page 57
1	NTIS, is that a way of	1	You see the first sentence of the
2	determining whether somebody is, in fact, a	2	paragraph?
3	registrant who is a customer of yours?	3	A. Yes.
4	A. It's National Technical	4	Q. The section sentence says
5	Information systems or Service, and it's a	5	"modified process to include the use of the NTIS
6	government government-run tool that can be	6	tape to assure license checks occurred at each
7	purchased, and it helps you your licenses	7	order rather than depending on customers to
8	typically expire yearly, but in this particular	8	provide new license at expiry."
9	case, if you have this tool, you can look at	9	And then you talk about increased
10	licenses in between that yearly expiration to	10	awareness and how you did the monthly monitoring
11	determine catch licenses that might have been	11	reports and various submissions around that,
12	suspended.	12	correct?
13	Q. You would agree that it's an	13	A. Yes.
14	important thing to make sure in a closed	14	Q. But all the way back prior to
15	system of controlled substance drug distribution	15	your time at Watson, even implementing
16	to make sure if you are a manufacturer	16	transaction-level order checks was something
	distributor that you are only selling drug to	17	that you thought was important and you
17		18	implemented, correct?
18	people who are	1 10	
	people who are MS. LEIBELL: Object to form.	19	MS. VANNI: Object to the form.
18	people who are		MS. VANNI: Object to the form. THE WITNESS: Yes, certain
18 19	people who are MS. LEIBELL: Object to form.	19	THE WITNESS: Yes, certain certain types of checks, yes.
18 19 20	people who are MS. LEIBELL: Object to form. BY MR. BUCHANAN:	19 20	THE WITNESS: Yes, certain
18 19 20 21	people who are MS. LEIBELL: Object to form. BY MR. BUCHANAN: Q permitted or licensed to	19 20 21	THE WITNESS: Yes, certain certain types of checks, yes.

	Page 58		Page 60
1	be a closed system of manufacturer,	1	Do you see that?
2	distribution, prescription, et cetera?	2	A. Yes.
3	A. Yes, that's correct.	3	Q. That was something you were
4	Q. And so if there's any leak in	4	doing that was you who was doing that?
5	that system, in that in all the players in	5	A. Working with customer service.
6	that system, then there's diversion risk, fair?	6	Q. And to run shipping history for
7	MS. VANNI: Object to form.	7	customers of concern?
8	THE WITNESS: Then there is a DEA	8	A. Mm-hmm.
9	violation.	9	Q. Okay. And then you also had
10	BY MR. BUCHANAN:	10	you. Bad word. Withdrawn.
11	Q. And diversion risk?	11	Watson also had a suspicious
12	MS. VANNI: Object to form.	12	order monitoring system that included a
13	THE WITNESS: Potentially.	13	multiplier, and then you would adjust the
14	BY MR. BUCHANAN:	14	multiplier on a customer-to-customer basis,
15	Q. I mean, you understand that as	15	correct?
16	somebody in the in the industry; if drug is	16	A. I don't believe we could adjust
17	being sold to somebody not permitted to get it,	17	it at a customer level. I think it was adjusted
18	by law, it's not a closed system, right?	18	overall for the class of trade.
19	A. Yes.	19	Q. So you had class-of-trade
20	Q. And when you apply for a	20	adjustments at Watson?
21	registration, when a manufacturer distributor	21	A. I believe it was by class of
22	•	22	*
	applies for a registration, they apply for that	23	trade. I'm not positive.
23	registration making the representation they're		Q. And class of trade, meaning
24	going to do everything they can to maintain a	24	Watson could have clients who were distributors,
	Page 59		Page 61
1	closed system, right?	1	correct?
2	MS. VANNI: Object to form.	2	A. Wholesalers would be one class of
3	THE WITNESS: Yes.	3	trade. It's basically, for the most part, DEA
4	BY MR. BUCHANAN:	4	license type.
5	Q. And I mean, that's been true	5	Q. Okay. And can you identify the
6	and that's not a change in the regulations,	6	various classes of trade?
7	that's been true for as long as you've been	7	A. Not all, but a wholesaler would
8	involved with controlled substances, correct?	8	be one. A chain drug store might be another. A
9	MS. VANNI: Object to form.	9	physician, not necessarily for Watson, but if
10	THE WITNESS: Yes.	10	we if you were to distribute to physicians,
11		11	
	BY MR. BUCHANAN:		that would be a class of trade, clinic or
12	Q. So let's go back, if we could, to	12	hospital, long-term care.
13	Watson. I realize I'm hopping around. Sorry	13	Q. And how about I'm sorry.
14	about that.	14	A. Long-term care. There's quite a
15	We'll go back to Watson.	15	few.
16	And then you note that during	16	Q. Okay. And how about just
17	your time at Watson, Watson was running shipping	17	independent pharmacy, is that a separate class
18	history for certain customers of concern, right?	18	of trade?
19	A. Just trying to see where your	19	A. Yes.
20	Q. Oh, I'm sorry, I realize I've	20	Q. And so during your time at
0.1	been hopping around.	21	Watson, you were responsible for the multipliers
21			6
22	"As part of the internal audits,	22	for the various class of trades, right?
	"As part of the internal audits, began to run shipping history for certain customers of concern."	22	A. Yes. Q. And when you say multiplier, what

Page 62 Page 64 1 does that mean? 1 Mm-hmm. 2 And what were the circumstances A. It's really a part of the SOM 2 O. 3 system, the percentage of orders that you would 3 of your -- you weren't brought in to take 4 look at. So, for example, when you create the 4 responsibility for the SOM system for Qualitest, 5 system, you want to make sure that you're 5 right? 6 6 catching orders that are legitimately of concern MS. VANNI: Object to form. 7 from a quantity perspective, but you also want 7 THE WITNESS: It was part of the 8 to make sure it's not catching every single 8 regulations, so ultimately I would have 9 9 responsibility for it. There's nothing 10 You know, you have to know --10 that requires the things that I have 11 it's almost like setting a threshold really. 11 responsibility for to report in to me, You have to know what -- where you want to cut 12 just more that I'm overseeing them. 12 13 that off. So when you first set up your system, 13 BY MR. BUCHANAN: 14 it could stop everything if you don't have a 14 Q. When you arrived at Qualitest, 15 multiplier that would dial down to where you 15 SOM was being handled by a different group, think is reasonable orders that you would want 16 16 right? 17 to investigate further. 17 A. Correct. 18 18 Q. So a system, essentially, that Q. And that was true for several 19 would identify orders that are red flags to be 19 years, right? 20 further investigated; would that be fair? 20 MS. VANNI: Object to form. A. Well, that's the SOM system, yes. THE WITNESS: It became more of a 21 21 22 O. Okay. And the way --22 partnership. 23 This is one piece of -- I'm 23 BY MR. BUCHANAN: A. 24 sorry -- this is one piece of the SOM system. 24 Q. In 2013, I think, after the Page 63 Page 65 1 1 Got you. So the multiplier was a meeting with the DEA, you were able to bring 2 component of an order monitoring system, fair? 2 that under your umbrella more directly, fair? 3 A. Yes. 3 MS. VANNI: Object to form. 4 THE WITNESS: Not sure exactly 4 Okay. And the multiplier was 5 used to set effectively where an order would get 5 when it occurred, but I think it was 6 6 flagged as an order to be investigated further, before then. I believe. 7 7 fair? BY MR. BUCHANAN: 8 For Watson, yes. 8 Q. When you actually had A. 9 9 responsibility for it? Yes. 10 10 And this was happening on the A. Yes, I believe so. 11 Watson, if you will, manufacturing side during 11 Q. Let's just get some -- some dates 12 12 your entire tenure there? kind of on a visual timeline, if you will. 13 13 Yes. You joined Qualitest in the A. 14 Q. Okay. 14 summer of 2011? 15 15 It was part of Watson's system. A. Yes. It may not be part of other systems, depending 16 16 17 on how it's developed. 17 18 Q. Okay, yeah, and I was referring 18 19 to, you know, Watson had the system that you've 19 20 described in your testimony and in this writing 20 21 during the entire time you were there? 21 22 A. Right. 22 23 23 Okay. Then you talk about your 24 time at Qualitest, right? 24



what it paid for it, it can get money back from the manufacturer, fair? MS. VANNI: Objection. THE WITNESS: From what I know, yes. BY MR. BUCHANAN: Q. That's a decent thumbnail sketch of what we're talking about with the business purpose primary business purpose of chargeback data, correct? A. Yes. Q. And as part of that, the distributor has got to come forward with its sales information to its end user customers, correct?	1 2 3 4 5 6 7 8 9 10 11 12	data as part of its suspicious order monitoring tools, correct? MS. VANNI: Objection. THE WITNESS: The company reviewed the potential of including chargeback data. At the time that I had left, we had not implemented it. I don't know if it was implemented after. BY MR. BUCHANAN: Q. Okay. We'll talk about that in a little more detail. A. Let me be clear, though. There is no, there's no DEA regulation that requires
MS. VANNI: Objection. THE WITNESS: From what I know, yes. BY MR. BUCHANAN: Q. That's a decent thumbnail sketch of what we're talking about with the business purpose primary business purpose of chargeback data, correct? A. Yes. Q. And as part of that, the distributor has got to come forward with its sales information to its end user customers,	3 4 5 6 7 8 9 10 11 12 13	MS. VANNI: Objection. THE WITNESS: The company reviewed the potential of including chargeback data. At the time that I had left, we had not implemented it. I don't know if it was implemented after. BY MR. BUCHANAN: Q. Okay. We'll talk about that in a little more detail. A. Let me be clear, though. There
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Q. That's a decent thumbnail sketch of what we're talking about with the business purpose primary business purpose of chargeback data, correct? A. Yes. Q. And as part of that, the distributor has got to come forward with its sales information to its end user customers,	7 8 9 10 11 12 13	left, we had not implemented it. I don't know if it was implemented after. BY MR. BUCHANAN: Q. Okay. We'll talk about that in a little more detail. A. Let me be clear, though. There
of what we're talking about with the business purpose primary business purpose of chargeback data, correct? A. Yes. Q. And as part of that, the distributor has got to come forward with its sales information to its end user customers,	8 9 10 11 12 13	don't know if it was implemented after. BY MR. BUCHANAN: Q. Okay. We'll talk about that in a little more detail. A. Let me be clear, though. There
purpose primary business purpose of chargeback data, correct? A. Yes. Q. And as part of that, the distributor has got to come forward with its sales information to its end user customers,	9 10 11 12 13	BY MR. BUCHANAN: Q. Okay. We'll talk about that in a little more detail. A. Let me be clear, though. There
chargeback data, correct? A. Yes. Q. And as part of that, the distributor has got to come forward with its sales information to its end user customers,	10 11 12 13	Q. Okay. We'll talk about that in a little more detail. A. Let me be clear, though. There
A. Yes. Q. And as part of that, the distributor has got to come forward with its sales information to its end user customers,	11 12 13	little more detail. A. Let me be clear, though. There
Q. And as part of that, the distributor has got to come forward with its sales information to its end user customers,	12 13	A. Let me be clear, though. There
distributor has got to come forward with its sales information to its end user customers,	13	
sales information to its end user customers,		is no there's no DEA regulation that require
•		is no there's no DEA regulation that requires
correct?	14	a company to include chargeback data in their
	15	SOM program.
A. Yes.	16	Q. Qualitest at the point in time
MS. VANNI: Objection.	17	when they implemented this and I guess
		there's some debate between you and I at the
		moment, and we'll just have to work through this
,		during the day, as to whether Qualitest ever
1 , 0	21	actually looked at chargeback data and used it
		as part of its suspicious order monitoring
		program.
MS. VANNI: Objection.	24	Is it your contention, as least
Page 71		Page 73
THE WITNESS: Yes, on some	1	as you are sitting here now, you don't recall
customers.	2	Qualitest doing that for its customers?
BY MR. BUCHANAN:	3	MS. VANNI: Object to form.
Q. Right, and some customers	4	THE WITNESS: When I was there,
A. Some don't participate.	5	we did not.
Q. Right. Your larger wholesalers	6	BY MR. BUCHANAN:
and distributors have chargeback agreements with	7	Q. Okay. Looking now to your
the manufacturers, correct?	8	description it's 1146.3, those are numbers in
MS. VANNI: Objection.	9	the top right corner, I'll reference them from
THE WITNESS: I don't know.	10	time to time, but it's Exhibit 2 for the
BY MR. BUCHANAN:	11	record this says "Upon arrival at Qualitest,
Q. Okay. Well, during your time at	12	I did not have responsibility for SOMs."
Qualitest, you did have access to chargeback	13	Was there a particular DEA issue
data, correct?	14	that you were brought in to deal with in
A. I looked at the data. I met with	15	Alabama?
financial individuals, and the data was not	16	MS. VANNI: Object to form.
helpful at that time.	17	THE WITNESS: I was brought in to
Q. Okay. We'll highlight that	18	basically implement a DEA program
answer and we'll circle back at some point	19	overall. Wasn't SOM specific.
during the day on that.	20	BY MR. BUCHANAN:
A. Yes.	21	Q. Who was the DEA compliance person
Q. You would agree that during the	22	that you replaced?
time that you were at Qualitest, the company	23	A. John Schultz.
implemented a system to incorporate chargeback	24	Q. Okay. If I understand correctly,
	THE WITNESS: Yes. BY MR. BUCHANAN: Q. And so the manufacturers then, as part of that reconciliation process, given end user customer information as part of the chargeback agreements, correct? MS. VANNI: Objection. Page 71 THE WITNESS: Yes, on some customers. BY MR. BUCHANAN: Q. Right, and some customers A. Some don't participate. Q. Right. Your larger wholesalers and distributors have chargeback agreements with the manufacturers, correct? MS. VANNI: Objection. THE WITNESS: I don't know. BY MR. BUCHANAN: Q. Okay. Well, during your time at Qualitest, you did have access to chargeback data, correct? A. I looked at the data. I met with financial individuals, and the data was not helpful at that time. Q. Okay. We'll highlight that answer and we'll circle back at some point during the day on that. A. Yes. Q. You would agree that during the time that you were at Qualitest, the company	THE WITNESS: Yes. BY MR. BUCHANAN: Q. And so the manufacturers then, as part of that reconciliation process, given end user customer information as part of the chargeback agreements, correct? MS. VANNI: Objection. Page 71 THE WITNESS: Yes, on some customers. BY MR. BUCHANAN: Q. Right, and some customers A. Some don't participate. Q. Right. Your larger wholesalers and distributors have chargeback agreements with the manufacturers, correct? MS. VANNI: Objection. THE WITNESS: I don't know. BY MR. BUCHANAN: Q. Okay. Well, during your time at Qualitest, you did have access to chargeback data, correct? A. I looked at the data. I met with financial individuals, and the data was not helpful at that time. Q. Okay. We'll highlight that answer and we'll circle back at some point during the day on that. A. Yes. Q. You would agree that during the time that you were at Qualitest, the company

	Page 74		Page 76
1	historic files show that Qualitest had separate	1	where you're referring to?
2	incidents with DEA which caused a bit of a stir,	2	MR. BUCHANAN: It's in this and
3	fair?	3	outside of this.
4	MS. VANNI: Objection.	4	THE WITNESS: License checks, I
5	THE WITNESS: Yes.	5	was not concerned. I know they were
6	BY MR. BUCHANAN:	6	checking the licenses.
7	Q. What were those?	7	BY MR. BUCHANAN:
8	A. Well, we had multiple	8	Q. On an order-by-order basis?
9	interactions with DEA. Are you referring to	9	A. I don't believe it was on an
10	prior to my coming?	10	order-by-order basis. DEA required at the time
11	Q. Prior to your coming, yes, the	11	and still requires really that you check the
12	issues that you were aware of that created a bit	12	license when you get a copy of the customer's
13	of a stir.	13	license, and that license is good for a year.
14	MS. VANNI: Object to form.	14	There's no DEA requirement, in other words, to
15	THE WITNESS: I was told that	15	purchase NTIS data.
16	there was a theft, and that that's why	16	Q. Okay. Fair enough. But all the
17	Mr. Schultz was being let go.	17	way back in the '90s, I mean, when you were at
18	BY MR. BUCHANAN:	18	Ciba-Geigy, I mean, Ciba-Geigy had an NTIS data
19	Q. Okay. And was that in the	19	stream that was checking orders as they were
20	Charlottesville facility or in the Huntsville	20	placed, correct?
21	facility?	21	A. It was available, yes, yes.
22	A. Huntsville.	22	Q. And that's how they were doing it
23	Q. Okay. And what was the other	23	back in the '90s?
24	incident?	24	MS. VANNI: Object to form.
24	merdent:	21	MS. VARIN. Object to form.
	Page 75		Page 77
1	A. That's the that's the only one	1	THE WITNESS: Yes.
2	· · · · · · · · · · · · · · · · · · ·		THE WITNESS YES
	I'm aware of prior to my coming.	2	
	I'm aware of prior to my coming. O Okay Are you aware of incidents	2	BY MR. BUCHANAN:
3	Q. Okay. Are you aware of incidents	2 3	BY MR. BUCHANAN: Q. Okay. And that's how Watson was
3 4	Q. Okay. Are you aware of incidents where the company was shipping products to	2 3 4	BY MR. BUCHANAN: Q. Okay. And that's how Watson was doing it before you before you got to Watson?
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	Page 78		Page 80
1	and they were reviewing what they needed to. My	1	off, they were on board anytime that I
2	concern was the perception that sales was the	2	interacted with them.
3	one handling it, and how that would be perceived	3	BY MR. BUCHANAN:
4	by others.	4	Q. Right.
5	Q. Right, because, I mean, you know	5	So once you showed them diligence
6	there's the salespeople are about selling,	6	that you had done or investigation that had
7	right?	7	been done, a review of data that had been
8	MS. VANNI: Object to form.	8	conducted, people were willing to accept the
9	THE WITNESS: That's what people	9	conclusion, fair?
10	would perceive, yes.	10	A. Yes.
11	BY MR. BUCHANAN:	11	Q. Okay. But you've got to do the
12	Q. I mean, that's not an	12	diligence, you've got to do the digging, you had
13	unreasonable perception, right?	13	to make the case?
14	MS. VANNI: Object to form.	14	MS. VANNI: Object to form.
15	THE WITNESS: It is a perception	15	THE WITNESS: Yes. We're not
16	that's out there	16	going to, you know, stop shipping to a
17	BY MR. BUCHANAN	17	customer without justification, sure.
18	Q. Right.	18	BY MR. BUCHANAN:
19	A. And regardless of how you	19	Q. So it's really hard to develop
20	know, salespeople have integrity, too, believe	20	that justification if you're not doing due
21	it or not.	21	diligence on customers, correct?
22	Q. Do you recall getting some	22	MS. VANNI: Object to form.
23	pushback from the sales side of Qualitest as you	23	THE WITNESS: No, because sales
24	started to implement and explore various SOMs	24	was contacting me. If they had a
1	Page 79	1	Page 81
1	initiatives	1 2	concern about a particular customer,
2	MS. VANNI: Objection. BY MR. BUCHANAN:	3	they were really, really good with bringing things forward and asking
4		4	questions, and so we were working
5	Q after your meeting with the DEA?	1 -	questions, and so we were working
J		5	together on it
6		5	together on it.
6 7	A. Questions from them? I think	6	BY MR. BUCHANAN:
7	A. Questions from them? I think that the education, we needed to educate a	6 7	BY MR. BUCHANAN: Q. Okay. It says here in early 2013
7 8	A. Questions from them? I think that the education, we needed to educate a little bit more. As far as how DEA looked at	6 7 8	BY MR. BUCHANAN: Q. Okay. It says here in early 2013 you received a program you received approval
7 8 9	A. Questions from them? I think that the education, we needed to educate a little bit more. As far as how DEA looked at the program not looked at the program, but	6 7 8 9	BY MR. BUCHANAN: Q. Okay. It says here in early 2013 you received a program you received approval to move the SOM program into DEA compliance.
7 8 9 10	A. Questions from them? I think that the education, we needed to educate a little bit more. As far as how DEA looked at the program not looked at the program, but how they how the regulation had changed over	6 7 8 9	BY MR. BUCHANAN: Q. Okay. It says here in early 2013 you received a program you received approval to move the SOM program into DEA compliance. Do you see that?
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7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Questions from them? I think that the education, we needed to educate a little bit more. As far as how DEA looked at the program not looked at the program, but how they how the regulation had changed over the years and how the perception of the regulation and the things that DEA would like to see changed over the years. Q. My question was simply whether you got some some pushback from sales as you were starting to implement, restrict and propose terminating certain customers. Do you recall that? MS. VANNI: Objection. THE WITNESS: I think you will always get pushback from sales at any	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY MR. BUCHANAN: Q. Okay. It says here in early 2013 you received a program you received approval to move the SOM program into DEA compliance. Do you see that? A. Yes. Q. Okay. Does that help refresh your recollection as to when that came under your umbrella? A. Yes, thank you. Q. Okay. So prior to that point in time, it was a sales function, right? MS. VANNI: Object to form. BY MR. BUCHANAN: Q. Sales, customer service? Excuse me.
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	Page 82		Page 84
1	Q. Right, so	1	BY MR. BUCHANAN:
2	A. With compliance input.	2	Q. I'm passing you, Ms. Norton, a
3	Q. And so in 2013, you brought it	3	copy of Exhibit 3 to your deposition. This is a
4	into the DEA compliance group.	4	letter from the U.S. Attorney, U.S. Department
5	Were you the head of DEA	5	of Justice, Joyce Vance, United States Attorney,
6	compliance at that point in time?	6	I guess for the Northern District of Alabama,
7	A. Yes.	7	it's dated September 30, 2014, 1060.2. If you
8	Q. And that was the title you held	8	could pull it up, please.
9	until you left?	9	And do you see before I guess
10	A. Yes.	10	you read the content of it, ma'am, do you see
11	Q. Why did you leave?	11	you're on this exchange?
12		12	A. Yes, I do.
13	A. A better position, promotion. I went to H.D. Smith as the VP.	13	
14		14	
	Q. Okay. There was a you left		contact from the Department of Justice on this
15	let's just look at Exhibit 2. Exhibit 2 is	15	particular correspondence from the U.S.
16	dated October 15th, 2014.	16	Attorney's Office?
17	Two weeks before this, you got	17	A. Yes.
18	that letter from the U.S. Attorney in Alabama	18	Q. It says "Ms. Hernandez, please
19	about egregious violations?	19	find attached the Notice of Intent to Seek Civil
20	A. Prior to me leaving?	20	Penalties."
21	MS. VANNI: Object to form.	21	Do you see that on the cover, the
22	BY MR. BUCHANAN:	22	cover e-mail?
23	Q. Yeah. Do you recall that?	23	A. Yes.
24	A. We had we had inspections by	24	Q. And this is September 30, 2014,
1	Page 83	1	Page 85
1	DEA throughout my time at Qualitest. I don't	1	it's a couple weeks, it looks like, before you
2	know which what instance you are referring	2	are engaging with H.D. Smith in your job search.
3	to, but we did have occasions where we had	3	Do you see that?
4	violation letters.	4	A. The date, yes, September 30.
5	Q. Okay. And do you recall do	5	Q. Is that correct?
6	you recall getting a letter not from the DEA,	6	A. Mm-hmm.
7	but from the U.S. Attorney directed to you,	7	Q. Okay. So you get this letter.
8	telling you that there were egregious violations	8	Please feel free to look at it. It's a
9	and you had a week to sit down with them to talk	9	follow-up letter to a teleconference you had had
10	about your fine?	10	a week earlier on September 22, 2014.
11	MS. VANNI: Object to form.	11	Do you see that?
4.0	THE WITNESS: I don't recall	12	A. Yes.
12	THE WITNESS. I doilt iccan		
13	that.	13	Q. Okay. It says, "The audit
			Q. Okay. It says, "The audit revealed alarming deviations of Schedule II and
13	that.	13	revealed alarming deviations of Schedule II and Schedule III controlled substances in violation
13 14	that. THE VIDEOGRAPHER: Counsel, could	13	revealed alarming deviations of Schedule II and
13 14 15	that. THE VIDEOGRAPHER: Counsel, could we go off the record just momentarily?	13 14 15	revealed alarming deviations of Schedule II and Schedule III controlled substances in violation
13 14 15 16	that. THE VIDEOGRAPHER: Counsel, could we go off the record just momentarily? MR. BUCHANAN: Yeah.	13 14 15 16	revealed alarming deviations of Schedule II and Schedule III controlled substances in violation of 21 CFR 1304.21, other statutes, you failed to
13 14 15 16 17	that. THE VIDEOGRAPHER: Counsel, could we go off the record just momentarily? MR. BUCHANAN: Yeah. THE VIDEOGRAPHER: Going off the	13 14 15 16 17	revealed alarming deviations of Schedule II and Schedule III controlled substances in violation of 21 CFR 1304.21, other statutes, you failed to account for and properly maintain records of the
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13 14 15 16 17 18	that. THE VIDEOGRAPHER: Counsel, could we go off the record just momentarily? MR. BUCHANAN: Yeah. THE VIDEOGRAPHER: Going off the record. The time is now 9:53 a m. (Brief recess.)	13 14 15 16 17 18 19	revealed alarming deviations of Schedule II and Schedule III controlled substances in violation of 21 CFR 1304.21, other statutes, you failed to account for and properly maintain records of the following." And then it's got a list of seven
13 14 15 16 17 18 19 20	that. THE VIDEOGRAPHER: Counsel, could we go off the record just momentarily? MR. BUCHANAN: Yeah. THE VIDEOGRAPHER: Going off the record. The time is now 9:53 a m. (Brief recess.) THE VIDEOGRAPHER: Back on the	13 14 15 16 17 18 19 20	revealed alarming deviations of Schedule II and Schedule III controlled substances in violation of 21 CFR 1304.21, other statutes, you failed to account for and properly maintain records of the following." And then it's got a list of seven items there. And, I'm sorry, are you still
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l	Page 86		Page 88
1	Q. And can you highlight the items,	1	correct?
2	please.	2	A. Mm-hmm.
3	So we see item one, Hydrocodone	3	Q "as demonstrated by, among
4	10, 325 milligrams, that's Hydrocodone	4	other things, deviations exceeding 9 million
5	10 milligrams, 325 milligrams of acetaminophen,	5	tablets."
6	is that what that would be?	6	Did I read that correctly?
7	A. Yes.	7	A. Yes.
8	Q. And so, you know, about roughly	8	Q. It continues, the follow on
9	1200 bottles unaccounted for, right?	9	paragraph, "GB's recordkeeping violations, in
10	A. Mm-hmm.	10	particular, as evidenced by the several-million
11	MS. VANNI: Objection to the	11	tablet deviations are" and what did they say?
12	form.	12	A. I'm sorry, where are you looking?
13	THE WITNESS: Doesn't necessarily	13	Failure to maintain
14	mean they were unaccounted for as much	14	Q. "GB's recordkeeping violations,
15	as the recordkeeping of them.	15	in particular"
16	BY MR. BUCHANAN:	16	A. Yes.
17	Q. Well, it says "GB," and GB is	17	Q "as evidenced by the
18	A. Generics Bidco.	18	several-million tablet deviation are," and what
19	Q. And Generics Bidco was one of the	19	do they say?
20	operating entities of Qualitest, correct?	20	A "egregious and evidence a
21	A. Yes.	21	complete disregard of GB's statutory and
22	Q. One of the registrants with the	22	regulatory obligations."
23	DEA, correct?	23	Q. That's not good.
24	A. Yes.	24	MS. VANNI: Object to form.
	1. 163.	2 4	MS. VAINNI. Object to form.
	Page 87		- 00
ı	1 490 07		Page 89
1	_	1	_
1 2	-	1 2	THE WITNESS: The way the DEA and/or the Attorney General words a
	Q. And there was another registrant		THE WITNESS: The way the DEA
2	Q. And there was another registrant with the DEA that also operated under Qualitest,	2	THE WITNESS: The way the DEA and/or the Attorney General words a violation letter is meant to meant to
2 3	Q. And there was another registrant with the DEA that also operated under Qualitest, correct? A. Yes.	2 3	THE WITNESS: The way the DEA and/or the Attorney General words a
2 3 4	Q. And there was another registrant with the DEA that also operated under Qualitest, correct? A. Yes.	2 3 4	THE WITNESS: The way the DEA and/or the Attorney General words a violation letter is meant to meant to be exaggerated for impact. BY MR. BUCHANAN:
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2 3 4 5 6	Q. And there was another registrant with the DEA that also operated under Qualitest, correct? A. Yes. Q. And what was the entity's name? A. Vintage Vintage Pharmaceuticals.	2 3 4 5 6	THE WITNESS: The way the DEA and/or the Attorney General words a violation letter is meant to meant to be exaggerated for impact. BY MR. BUCHANAN: Q. "Egregious and evidence of a complete disregard of your statutory and
2 3 4 5 6 7	Q. And there was another registrant with the DEA that also operated under Qualitest, correct? A. Yes. Q. And what was the entity's name? A. Vintage Vintage	2 3 4 5 6 7	THE WITNESS: The way the DEA and/or the Attorney General words a violation letter is meant to meant to be exaggerated for impact. BY MR. BUCHANAN: Q. "Egregious and evidence of a complete disregard of your statutory and regulatory obligation," that's not good, right?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. And there was another registrant with the DEA that also operated under Qualitest, correct? A. Yes. Q. And what was the entity's name? A. Vintage Vintage Pharmaceuticals. Q. Right. So what we see here are some 1200 bottles of Hydrocodone with 10 milligrams, 1300 bottles of hydrocodone seven and a half milligrams, more in different in different allocations. 816 bottles of Oxycodone. What's Oxycodone 30 milligrams, ma'am? A. What is it? Q. Yeah. A. I don't Q. Is it a generic of Oxycontin? A. Yes. Q. Okay. And then on the next page,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	THE WITNESS: The way the DEA and/or the Attorney General words a violation letter is meant to meant to be exaggerated for impact. BY MR. BUCHANAN: Q. "Egregious and evidence of a complete disregard of your statutory and regulatory obligation," that's not good, right? MS. VANNI: Object to form. THE WITNESS: It's not it's not really descriptive of the situation. BY MR. BUCHANAN: Q. It's certainly not the way a company who is a registrant in a closed system of controlled substance distribution should be contacting itself, right? MS. VANNI: Object to form. THE WITNESS: These letters are also meant to point out violations BY MR. BUCHANAN: Q. Can you answer my question?

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1	substance is supposed to be behaving, correct?	1	MS. VANNI: Objection.
2	MS. VANNI: Object to form.	2	THE WITNESS: of a DEA
3	THE WITNESS: You don't want any	3	inspection.
4	violations.	4	BY MR. BUCHANAN:
5	BY MR. BUCHANAN:	5	Q. Right. So you would have had
6	Q. Okay. You certainly don't want	6	interactions with the DEA on this issue before
7	to engage in egregious and complete disregard of	7	you got
8	your statutory and regulatory obligations, fair?	8	A. The local office, yes.
9	MS. VANNI: Object to form.	9	Q. And what fine did Qualitest pay
10	THE WITNESS: And we were not.	10	in connection with this?
11	BY MR. BUCHANAN:	11	MS. VANNI: Object to form.
12	Q. Okay. And they said you had a	12	THE WITNESS: I'm not sure.
13	week to sit down with them to negotiate your	13	BY MR. BUCHANAN:
14	fine, right?	14	Q. Were you a part of those
15	A. Yes.	15	discussions?
16	Q. And were you part of those	16	A. No, I think I had left already.
17	discussions?	17	I don't recall.
18	A. I don't recall.	18	Q. Okay. What happened after this
19	Q. Because this is not this	19	letter?
20	wasn't just the first notice you had from the	20	MS. VANNI: Object to form.
21	U.S. Attorney, right?	21	THE WITNESS: After any letter
22	MS. VANNI: Object to form.	22	and, again, I didn't recall this
23	THE WITNESS: I don't know	23	instance offhand and I know that the
24	whether we had notices from the Attorney	24	quantities that are listed here, the
	Page 91		Page 93
1	General or violation letters. We did	1	issues were surrounding complaint
2	have other violation letters, but I	2	samples which get returned to the
3	don't know if the Attorney General was	3	company from customers in various
4	involved. Offhand, I don't recall.	4	conditions and, for example, you might
5	BY MR. BUCHANAN:	5	receive a liquid in that came in in a
6	Q. Right.	6	bottle that the bottle is broken and
7	You had a call with certainly the	7	there's glass.
8	U.S. Attorney a week before this, right?	8	So, I mean, these are not liquid,
9	A. I don't know for sure.	9	but the complaints that come back from
10	Q. First paragraph, last sentence.	10	customers are not usually in very good
1	A 77		
11	A. Yes.	11	form, and that's what many of these were
11 12	A. Yes. Q. Okay. You had a call with the	11 12	
			form, and that's what many of these were
12	Q. Okay. You had a call with the U.S. Attorney before this?	12	form, and that's what many of these were related to, I believe.
12 13	Q. Okay. You had a call with the U.S. Attorney before this?	12 13	form, and that's what many of these were related to, I believe. BY MR. BUCHANAN:
12 13 14	Q. Okay. You had a call with the U.S. Attorney before this? A. So the call would have been by	12 13 14	form, and that's what many of these were related to, I believe. BY MR. BUCHANAN: Q. 9 million pills?
12 13 14 15	Q. Okay. You had a call with the U.S. Attorney before this? A. So the call would have been by the looks of it here, the call would have been	12 13 14 15	form, and that's what many of these were related to, I believe. BY MR. BUCHANAN: Q. 9 million pills? A. Mm-hmm, yes.
12 13 14 15 16	Q. Okay. You had a call with the U.S. Attorney before this? A. So the call would have been by the looks of it here, the call would have been to say do we want this sent by e-mail, do we	12 13 14 15 16	form, and that's what many of these were related to, I believe. BY MR. BUCHANAN: Q. 9 million pills? A. Mm-hmm, yes. Q. 9 million pills, you're claiming,
12 13 14 15 16 17	Q. Okay. You had a call with the U.S. Attorney before this? A. So the call would have been by the looks of it here, the call would have been to say do we want this sent by e-mail, do we want it sent by mail, et cetera.	12 13 14 15 16 17	form, and that's what many of these were related to, I believe. BY MR. BUCHANAN: Q. 9 million pills? A. Mm-hmm, yes. Q. 9 million pills, you're claiming, were cracked bottles?
12 13 14 15 16 17	Q. Okay. You had a call with the U.S. Attorney before this? A. So the call would have been by the looks of it here, the call would have been to say do we want this sent by e-mail, do we want it sent by mail, et cetera. At that point, we probably would	12 13 14 15 16 17 18	form, and that's what many of these were related to, I believe. BY MR. BUCHANAN: Q. 9 million pills? A. Mm-hmm, yes. Q. 9 million pills, you're claiming, were cracked bottles? MS. VANNI: Object to form. THE WITNESS: No, no, these were
12 13 14 15 16 17 18	Q. Okay. You had a call with the U.S. Attorney before this? A. So the call would have been by the looks of it here, the call would have been to say do we want this sent by e-mail, do we want it sent by mail, et cetera. At that point, we probably would not know the details of what was included in it until it came.	12 13 14 15 16 17 18 19	form, and that's what many of these were related to, I believe. BY MR. BUCHANAN: Q. 9 million pills? A. Mm-hmm, yes. Q. 9 million pills, you're claiming, were cracked bottles? MS. VANNI: Object to form. THE WITNESS: No, no, these were not bottle these, in particular, that
12 13 14 15 16 17 18 19 20	Q. Okay. You had a call with the U.S. Attorney before this? A. So the call would have been by the looks of it here, the call would have been to say do we want this sent by e-mail, do we want it sent by mail, et cetera. At that point, we probably would not know the details of what was included in it until it came. Q. And you would have had	12 13 14 15 16 17 18 19 20	form, and that's what many of these were related to, I believe. BY MR. BUCHANAN: Q. 9 million pills? A. Mm-hmm, yes. Q. 9 million pills, you're claiming, were cracked bottles? MS. VANNI: Object to form. THE WITNESS: No, no, these were not bottle these, in particular, that are listed here are not liquid, but I'm
12 13 14 15 16 17 18 19 20 21	Q. Okay. You had a call with the U.S. Attorney before this? A. So the call would have been by the looks of it here, the call would have been to say do we want this sent by e-mail, do we want it sent by mail, et cetera. At that point, we probably would not know the details of what was included in it until it came.	12 13 14 15 16 17 18 19 20 21	form, and that's what many of these were related to, I believe. BY MR. BUCHANAN: Q. 9 million pills? A. Mm-hmm, yes. Q. 9 million pills, you're claiming, were cracked bottles? MS. VANNI: Object to form. THE WITNESS: No, no, these were not bottle these, in particular, that

Page 94 Page 96 1 Q. Okay. 1 pills? You don't remember that? 2 2 A. So partial tablets in MS. VANNI: Object to form. 3 prescription bottles dumped into containers, 3 THE WITNESS: I may have been 4 loose, you know, that's what we're dealing with Δ involved in it during my time there, but 5 from a complaint perspective when those are 5 I don't recall any of it. I don't want 6 6 to miscomment on what I did or didn't returned to us. 7 Okay. Well, specifically on this 7 Q. do 8 8 one, were you a part of the investigation around BY MR. BUCHANAN: 9 9 Q. As part of your separation with 10 I don't recall. 10 the company in 2014, did you have interactions A. 11 O. Who handled the investigation? 11 with management in any way relating to this 12 12 particular event? A. I don't know. It was for the 13 13 distribution, Generics Bidco, it would be for MS. VANNI: Object to form. 14 14 the distribution center, so I would assume THE WITNESS: I would have 15 someone in distribution, someone who had been 15 interactions with management about any 16 left on my team. I don't know who else. 16 violation that the company received, so 17 17 I would assume that I did. Again, I Okay. And so after this 18 18 interaction at least -- and I haven't been able don't know who or -- I don't recall the 19 19 to see -- withdrawn. details of it. 20 20 MR. BUCHANAN: You asked for a After you received this letter, 21 we certainly know you're in at least more -- you 21 five-minute break, and I'm good now, 22 send your resume out, you commence a screening 22 thanks. 23 23 process with H.D. Smith to pursue employment MS. VANNI: Okay. 24 24 THE VIDEOGRAPHER: Going off the there, fair? Page 95 Page 97 1 1 A. No. not fair. This letter would record. The time now is 10:06 a m. 2 2 have nothing to do with me leaving the company. (Brief recess.) 3 After the amount of time that I have in a DEA 3 THE VIDEOGRAPHER: Now going back 4 4 on the record. The time is 10:20 a m. compliance role, a violation letter would not 5 5 BY MR. BUCHANAN: cause me to leave a company. 6 6 Q. And so -- that's what I'm trying O. As I said, you can set aside that 7 7 last exhibit. You've worked for several to understand. 8 We have this letter, you're not 8 manufacturers, distributors who are the subject 9 9 involved in the investigation around the letter, of the litigation that brings us here today. 10 10 and you're the head of DEA compliance? I'm focusing most of my questions 11 11 MS. VANNI: Object to form. during your time on Qualitest, so I've got a 12 THE WITNESS: I don't know if I 12 period of time to do that. Other people may 13 13 have some questions about other points in time. was or not. I just don't recall it. 14 It's been a while. I would assume --14 A. Yes. 15 15 Q. But you spent some time, I BY MR. BUCHANAN: 16 16 assume, meeting with counsel before today to You had some recollection, ma'am, 17 about, you know, getting the ANDA meeting with 17 kind of run through this? 18 the DEA back in 2008, 2009 -- or the Anda 18 A. Yes, I did. 19 19 meeting, excuse me, in 2008, 2009. You don't Q. Okay. Who -- who did you speak with by the entity, counsel for? 20 remember a letter from the U.S. Attorney saying 20 21 21 A. Counsel for Endo, counsel for we've got to sit down and talk about potentially 22 millions of dollars in fines relating to 22 H.D. Smith and counsel for Watson. 23 23 Q. Okay. Separate counsel for Anda egregious, alarming, complete deviations and 24 failure to account for more than 9 million 24 or same counsel for both?

	Page 98		Page 100
1	A. Briefly for Anda. Briefly for	1	A. I do.
2	Anda.	2	Q. What is the business of Noramco?
3	Q. Okay. And so that was separate	3	A. They are a chemical active
4	counsel for Anda?	4	ingredient manufacturer.
5	A. Yes.	5	Q. So they make the API?
6	Q. Okay. And all in one session or	6	A. Yes.
7	in multiple sessions?	7	Q. They make APIs that are
8	MS. VANNI: Object to form.	8	controlled substances?
9	THE WITNESS: Multiple.	9	A. Yes.
10	BY MR. BUCHANAN:	10	Q. And which ones do they make?
11	Q. Okay. When did you first start	11	A. They make several. Hydrocodone,
12	meeting?	12	oxycodone, Tapentadol.
13	A. About a month ago.	13	Q. And oxycodone would be the active
14	Q. Okay. And let's talk about kind	14	pharmaceutical ingredient in is API an active
15	of in-person meetings first.	15	pharmaceutical ingredient?
16	How many of those did you have?	16	A. Yes, it is.
17	A. I think three with Endo, two with	17	Q. Okay. So oxycodone is the active
18	H.D. Smith and one with Watson.	18	pharmaceutical ingredient in Oxycontin?
19	Q. Each one of these several hours?	19	A. Yes.
20	MS. VANNI: Object to form.	20	Q. And hydrocodone would be an
21	THE WITNESS: Yes.	21	active pharmaceutical ingredient in products
22	BY MR. BUCHANAN:	22	like Vicodin?
23	Q. Okay. You don't currently work	23	A. Yes.
24	for any of the firms whose counsel you met with,	24	Q. Okay. And so we'll look at some
	Page 99		Page 101
1	correct?	1	documents today where they're referenced by
2	A. No, I do not.	2	hydrocodone APAP or oxycodone.
3	Q. When I said firms, I mean either	3	When we see hydrocodone APAP, we
4	Endo or H.D. Smith or Watson, correct?	4	can think of that as Vicodin?
5	A. No, do not.	5	MS. VANNI: Objection.
6	Q. Was your current employer present	6	THE WITNESS: Hydrocodone
7	at any of those meetings?	7	acetaminophen, yes.
8	A. Yes.	8	BY MR. BUCHANAN:
9	Q. Okay. All of them?	9	Q. Okay. APAP is an abbreviation in
10	A. No.	10	the pharmaceutical industry for acetaminophen,
11	Q. Okay. So that would be an	11	which would retail as Tylenol in its if it
12	additional meeting or that person attended	12	was just acetaminophen, right?
13	certain of the meetings?	13	A. Yes.
14	A. Attended certain.	14	Q. Okay. When you combine
15	Q. Okay.	15	essentially Tylenol with the controlled
16	A. And there was an additional	16	substance hydrocodone, that goes by a brand name
17	meeting with them separately.	17	of Vicodin, correct?
18	Q. Okay. And your current employer	18	A. Sometimes, yes.
ΤQ	Lana from Eulideit 1 in Manage and	19	Q. Well, Vicodin is hydrocodone and
18	I see from Exhibit 1 is Noramco?		
	A. Yes, that's correct.	20	acetaminophen combined, correct?
19		20 21	A. Yes.
19 20	A. Yes, that's correct.		
19 20 21	A. Yes, that's correct.Q. Out of Wilmington, Delaware?	21	A. Yes.

	Page 102		Page 104
1	And so the business of Noramco is	1	Q. And did it?
2	the manufacturer of the if you will, the	2	A. Yes.
3	active controlled substance that gets ultimately	3	Q. What were you shown?
4	put into the tablets that are stamped by	4	MS. VANNI: Object to the form.
5	manufacturers like Qualitest, correct?	5	I'm going to instruct her not to answer
6	A. Yes, that's correct.	6	as to what she was shown. That's
7	MS. HERGENROTHER: Objection.	7	clearly work product.
8	MR. BUCHANAN: Who is on the line	8	MR. BUCHANAN: It's actually not.
9	and raising that objection for which	9	I mean, frankly, if you showed her
10	defendant?	10	anything that refreshed her
11	MS. HERGENROTHER: It's Jenny	11	recollection, I'm entitled under Rule
12	Hergenrother for Noramco, Inc.	12	608 or 611, whatever it is, to copies of
13	BY MR. BUCHANAN:	13	whatever she was shown, so
14	Q. All right. So we were running	14	MS. VANNI: I'm going to instruct
15	through these meetings you had, several hours,	15	her not to answer as exactly to what she
16	several meetings, several hours at each meeting	16	was shown.
17	for several meetings, correct?	17	You can ask her how her
18	MS. VANNI: Object to form.	18	recollection was refreshed or if her
19	THE WITNESS: Yes, correct.	19	recollection was refreshed, but or if
20	BY MR. BUCHANAN:	20	she remembers specific documents, but
21	Q. All right. Good. I've got seven	21	she is not going to tell you specific
22	meetings over the last month?	22	documents that she was shown.
23	A. Approximately.	23	MR. BUCHANAN: If the witness'
24	Q. Okay. And these are	24	recollection was refreshed by documents
24	Q. Okay. And these are	24	reconection was refreshed by documents
	Page 103		Page 105
1	face-to-face, right?	1	that you showed her, I'm entitled to
2	MS. KOSKI: Object to form.	2	have them so that I can appropriately
3	THE WITNESS: Most, yes.	3	examine her on her refreshed
4	BY MR. BUCHANAN:	4	recollection. That's the law.
5	Q. Okay. And then you probably had	5	MS. VANNI: Counsel, this you
6	some video conference-type stuff where you	6	know that the documents that she is
7	shared screens. Did that happen, too?		
/		7	shown by counsel in preparation for
	** '		shown by counsel in preparation for deposition are protected by
8 9	MS. VANNI: Object to form.	7 8 9	deposition are protected by
8	MS. VANNI: Object to form. THE WITNESS: No.	8	deposition are protected by attorney-client and work product.
8	MS. VANNI: Object to form. THE WITNESS: No. BY MR. BUCHANAN:	8 9	deposition are protected by attorney-client and work product. MR. BUCHANAN: We disagree.
8 9 10 11	MS. VANNI: Object to form. THE WITNESS: No. BY MR. BUCHANAN: Q. No?	8 9 10	deposition are protected by attorney-client and work product. MR. BUCHANAN: We disagree. Certainly where it refreshes your
8 9 10 11 12	MS. VANNI: Object to form. THE WITNESS: No. BY MR. BUCHANAN: Q. No? Did you have some teleconferences	8 9 10 11	deposition are protected by attorney-client and work product. MR. BUCHANAN: We disagree. Certainly where it refreshes your recollection.
8 9 10 11 12 13	MS. VANNI: Object to form. THE WITNESS: No. BY MR. BUCHANAN: Q. No? Did you have some teleconferences or phone calls?	8 9 10 11 12	deposition are protected by attorney-client and work product. MR. BUCHANAN: We disagree. Certainly where it refreshes your recollection. BY MR. BUCHANAN:
8 9 10 11 12 13	MS. VANNI: Object to form. THE WITNESS: No. BY MR. BUCHANAN: Q. No? Did you have some teleconferences or phone calls? A. Yes.	8 9 10 11 12 13 14	deposition are protected by attorney-client and work product. MR. BUCHANAN: We disagree. Certainly where it refreshes your recollection. BY MR. BUCHANAN: Q. So please describe the subject
8 9 10 11 12 13 14	MS. VANNI: Object to form. THE WITNESS: No. BY MR. BUCHANAN: Q. No? Did you have some teleconferences or phone calls? A. Yes. Q. Okay. Did that start before the	8 9 10 11 12 13	deposition are protected by attorney-client and work product. MR. BUCHANAN: We disagree. Certainly where it refreshes your recollection. BY MR. BUCHANAN: Q. So please describe the subject matter
8 9 10 11 12 13 14 15	MS. VANNI: Object to form. THE WITNESS: No. BY MR. BUCHANAN: Q. No? Did you have some teleconferences or phone calls? A. Yes. Q. Okay. Did that start before the last month?	8 9 10 11 12 13 14 15	deposition are protected by attorney-client and work product. MR. BUCHANAN: We disagree. Certainly where it refreshes your recollection. BY MR. BUCHANAN: Q. So please describe the subject matter MR. BUCHANAN: You're instructing
8 9 10 11 12 13 14 15 16	MS. VANNI: Object to form. THE WITNESS: No. BY MR. BUCHANAN: Q. No? Did you have some teleconferences or phone calls? A. Yes. Q. Okay. Did that start before the last month? A. I'm not positive.	8 9 10 11 12 13 14 15 16 17	deposition are protected by attorney-client and work product. MR. BUCHANAN: We disagree. Certainly where it refreshes your recollection. BY MR. BUCHANAN: Q. So please describe the subject matter MR. BUCHANAN: You're instructing her not to answer, correct?
8 9 10 11 12 13 14 15 16 17	MS. VANNI: Object to form. THE WITNESS: No. BY MR. BUCHANAN: Q. No? Did you have some teleconferences or phone calls? A. Yes. Q. Okay. Did that start before the last month? A. I'm not positive. Q. Okay.	8 9 10 11 12 13 14 15 16 17	deposition are protected by attorney-client and work product. MR. BUCHANAN: We disagree. Certainly where it refreshes your recollection. BY MR. BUCHANAN: Q. So please describe the subject matter MR. BUCHANAN: You're instructing her not to answer, correct? MS. VANNI: I am as to what
8 9 10 11 12 13 14 15 16 17 18	MS. VANNI: Object to form. THE WITNESS: No. BY MR. BUCHANAN: Q. No? Did you have some teleconferences or phone calls? A. Yes. Q. Okay. Did that start before the last month? A. I'm not positive. Q. Okay. A. I don't think so.	8 9 10 11 12 13 14 15 16 17 18	deposition are protected by attorney-client and work product. MR. BUCHANAN: We disagree. Certainly where it refreshes your recollection. BY MR. BUCHANAN: Q. So please describe the subject matter MR. BUCHANAN: You're instructing her not to answer, correct? MS. VANNI: I am as to what specific documents she was shown.
8 9 10 11 12 13 14 15 16 17 18 19 20	MS. VANNI: Object to form. THE WITNESS: No. BY MR. BUCHANAN: Q. No? Did you have some teleconferences or phone calls? A. Yes. Q. Okay. Did that start before the last month? A. I'm not positive. Q. Okay. A. I don't think so. Q. Did you review some documents to	8 9 10 11 12 13 14 15 16 17 18 19 20	deposition are protected by attorney-client and work product. MR. BUCHANAN: We disagree. Certainly where it refreshes your recollection. BY MR. BUCHANAN: Q. So please describe the subject matter MR. BUCHANAN: You're instructing her not to answer, correct? MS. VANNI: I am as to what specific documents she was shown. BY MR. BUCHANAN:
8 9 10 11 12 13 14 15 16 17 18 19 20 21	MS. VANNI: Object to form. THE WITNESS: No. BY MR. BUCHANAN: Q. No? Did you have some teleconferences or phone calls? A. Yes. Q. Okay. Did that start before the last month? A. I'm not positive. Q. Okay. A. I don't think so. Q. Did you review some documents to get ready for today?	8 9 10 11 12 13 14 15 16 17 18 19 20 21	deposition are protected by attorney-client and work product. MR. BUCHANAN: We disagree. Certainly where it refreshes your recollection. BY MR. BUCHANAN: Q. So please describe the subject matter MR. BUCHANAN: You're instructing her not to answer, correct? MS. VANNI: I am as to what specific documents she was shown. BY MR. BUCHANAN: Q. Okay. Let's talk about, then,
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MS. VANNI: Object to form. THE WITNESS: No. BY MR. BUCHANAN: Q. No? Did you have some teleconferences or phone calls? A. Yes. Q. Okay. Did that start before the last month? A. I'm not positive. Q. Okay. A. I don't think so. Q. Did you review some documents to get ready for today? A. I was shown some documents, yes.	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	deposition are protected by attorney-client and work product. MR. BUCHANAN: We disagree. Certainly where it refreshes your recollection. BY MR. BUCHANAN: Q. So please describe the subject matter MR. BUCHANAN: You're instructing her not to answer, correct? MS. VANNI: I am as to what specific documents she was shown. BY MR. BUCHANAN: Q. Okay. Let's talk about, then, the areas in which you were shown documents.
8 9 10 11 12 13 14 15 16 17 18 19 20 21	MS. VANNI: Object to form. THE WITNESS: No. BY MR. BUCHANAN: Q. No? Did you have some teleconferences or phone calls? A. Yes. Q. Okay. Did that start before the last month? A. I'm not positive. Q. Okay. A. I don't think so. Q. Did you review some documents to get ready for today?	8 9 10 11 12 13 14 15 16 17 18 19 20 21	deposition are protected by attorney-client and work product. MR. BUCHANAN: We disagree. Certainly where it refreshes your recollection. BY MR. BUCHANAN: Q. So please describe the subject matter MR. BUCHANAN: You're instructing her not to answer, correct? MS. VANNI: I am as to what specific documents she was shown. BY MR. BUCHANAN: Q. Okay. Let's talk about, then,

	Page 106		Page 108
1	A. Yes.	1	Endo, you went off to H.D. Smith?
2	Q. Okay. And what areas of subject	2	A. Yes.
3	matter were those documents?	3	Q. Had a little consulting gig after
4	A. Oh, gosh. E-mails, inspection	4	that, right?
5	information.	5	MS. VANNI: Object to form.
6	Q. Documents you wrote?	6	THE WITNESS: I was consulting.
7	A. Yes.	7	BY MR. BUCHANAN:
8	Q. Documents you received?	8	Q. For nine months?
9	A. In some cases, yes.	9	A. Yes.
10	Q. Documents that you don't appear	10	Q. I didn't say that disparagingly.
11	to have been copied on but were, nonetheless, in	11	I'm just trying to fill out your full history so
12	your area of responsibility?	12	we can drill down a little bit.
13	MS. VANNI: Objection.	13	You were at H.D. Smith from 2014
14	THE WITNESS: Yeah, yes.	14	to 2016. From 2016 to 2017, you remained
15	BY MR. BUCHANAN:	15	Pennsylvania based or came back here to
16	Q. Okay. Were you shown documents	16	Pennsylvania
17	by counsel for any of the other defendants?	17	A. Yes.
18	A. Other than Endo?	18	Q and were a regulatory
19	Q. Yes.	19	consultant or compliance consultant from here,
20	A. Yes.	20	correct?
21	Q. Okay. Which defendant?	21	A. Correct.
22	A. H.D. Smith.	22	Q. Did you consult for any of your
23	Q. And did those refresh your	23	former clients during that period of time? I
24	recollection as well?	24	shouldn't withdrawn.
	Page 107		Page 109
1	A. Yes.	1	Did you consult for any of the
2	Q. Okay. And what subject areas	2	former employers we've already talked about
3	were those?	3	during that period of time?
4	A. SOM. I think that's mostly	4	A. I did not.
5	SOM.	5	Q. Okay. Since leaving Endo, have
6	Q. Okay. And what documents were	6	you done consulting for Endo?
7	you shown?	7	MS. VANNI: Object to the form.
8	MR. LEEDER: Objection?	8	THE WITNESS: No.
9	MR. BUCHANAN: We've already had	9	BY MR. BUCHANAN:
10	the instruction on the record. You're	10	Q. Since leaving H.D. Smith, have
11	going to have to instruct the witness	11	you done consulting for H.D. Smith?
12	not to answer.	12	A. No.
13	MR. LEEDER: I've already raised	13	Q. Since leaving I said Endo. I
14	this objection with Mr. Young, and I	14	should have said Qualitest.
15	will ask the witness not to answer the	15	Since leaving Qualitest, have you
16	question.	16	done work for Qualitest?
17	MR. BUCHANAN: Unless he	17	A. No.
	instructs you not to answer the I	18	Q. Okay. So, too, for any of the
18		19	other manufacturers, distributors you've worked
18 19	just I need to be clear, are you	1 19	,
	just I need to be clear, are you instructing witness not to	20	for, correct?
19			
19 20	instructing witness not to	20	for, correct?
19 20 21	instructing witness not to MR. LEEDER: I'm instructing the	20 21	for, correct? A. Correct.

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1	Did you work for any	1	A. Closer to closer to my
2	manufacturers of controlled substances or	2	leaving, closer to the end of my work. Mostly I
3	distributors of controlled substances that you	3	did not report to him for a long period of time.
4	believe are defendants in this case?	4	Q. Okay. So you had different
5	A. No.	5	people you reported to over time, but at the end
6	Q. Okay. Did you work for any	6	of your tenure at Qualitest, the person you
7	manufacturers or distributors of controlled	7	reported to is the chief operating officer,
8	substances?	8	correct?
9	A. Yes.	9	A. Yes.
10	Q. Who?	10	Q. Okay. That person was for the
11	A. For Neos Therapeutics.	11	pharmaceutical division?
12	Q. Okay. And they brought you on	12	A. Yes.
13	board?	13	Q. Okay. And who was that person?
14	A. Yes, they did.	14	A. Don Degoyler.
15	Q. Okay. Texas was too far, so you	15	Q. Okay. And you had interactions
16	lasted for a year and then you came back here?	16	with him from time to time?
17	A. No.	17	MS. VANNI: Object to form.
18	Q. Okay.	18	THE WITNESS: Occasionally.
19	A. I did not relocate to Texas. I	19	BY MR. BUCHANAN:
20	worked from from my home in Bethlehem and	20	Q. Let's talk about Qualitest.
21	went to Texas one week a month.	21	Qualitest is a manufacturer and
22	Q. Okay. All right. So I think we	22	distributor of controlled substances, true?
23	understand at this point, ma'am, to recap,	23	A. They were.
24	you've got about 30 years' experience dealing	24	Q. Among other things?
	you to got accuracy yours emperioned acuming		Q. I mong out a mingo.
	Page 111		Page 113
1	with controlled substances in some capacity or	1	A. They were, yes.
2	another, fair?	2	Q. Okay. Roughly 70% of their
3	A. Yes.	3	business was controlled substances, do you
4	Q. At various points at time and at		
	Q. At various points at time and at	4	remember that?
5	times I'm going to drill down on in particular	4 5	
5 6	*		MS. VANNI: Objection.
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6	times I'm going to drill down on in particular during your time at Qualitest, you were the DEA	5 6	MS. VANNI: Objection. THE WITNESS: If I had to guess,
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	Page 114		Page 116
1	A. They did not.	1	drugs?
2	Q. So Charlotte, North Carolina,	2	MS. VANNI: Objection.
3	Huntsville, Alabama is where they're making all	3	THE WITNESS: I would not
4	these pills, correct?	4	classify them as dangerous. When used
5	MS. VANNI: Object to form.	5	appropriately, they're products that are
6	THE WITNESS: That's where they	6	approved by FDA for legitimate purposes.
7	had facilities, yes.	7	I wouldn't necessarily characterize them
8	BY MR. BUCHANAN:	8	as dangerous.
9	Q. Okay. And to be clear, I mean,	9	BY MR. BUCHANAN:
10	billions and billions of pills, right?	10	Q. Okay. Got to keep them in
11	MS. VANNI: Object to form.	11	vaults, right?
12	THE WITNESS: I didn't keep track	12	A. Yes.
13	of total quantities.	13	Q. Cages, right?
14	BY MR, BUCHANAN:	14	A. Yes.
15	Q. Do you have do you have a	15	Q. Two people watching everybody at
16	sense that they were making a lot of them?	16	all times, right?
17	MS. VANNI: Object to form.	17	MS. VANNI: Object to form.
18	THE WITNESS: There was a	18	BY MR. BUCHANAN:
19	diverse diverse range of products.	19	Q. Right?
20	BY MR. BUCHANAN:	20	A. In some instances, two people.
21	Q. Okay. I mean, you've been to the	21	Q. Don't put on the outside of the
22	manufacturing facilities, right?	22	box what's on the inside of the box because
23	A. Mm-hmm.	23	they're very prone to being stolen, diverted,
24	Q. Yes?	24	abused, right?
	Page 115		Page 117
1			
	A. Yes.	1	MS. VANNI: Object to form.
2	Q. Sorry. We're kind of getting	2	THE WITNESS: There is a
2	Q. Sorry. We're kind of getting loose there.		
2 3 4	Q. Sorry. We're kind of getting loose there. And I mean, these controlled	2 3 4	THE WITNESS: There is a diversion potential, abuse potential, yes.
2	Q. Sorry. We're kind of getting loose there. And I mean, these controlled substances and let's dial back for a second.	2 3	THE WITNESS: There is a diversion potential, abuse potential,
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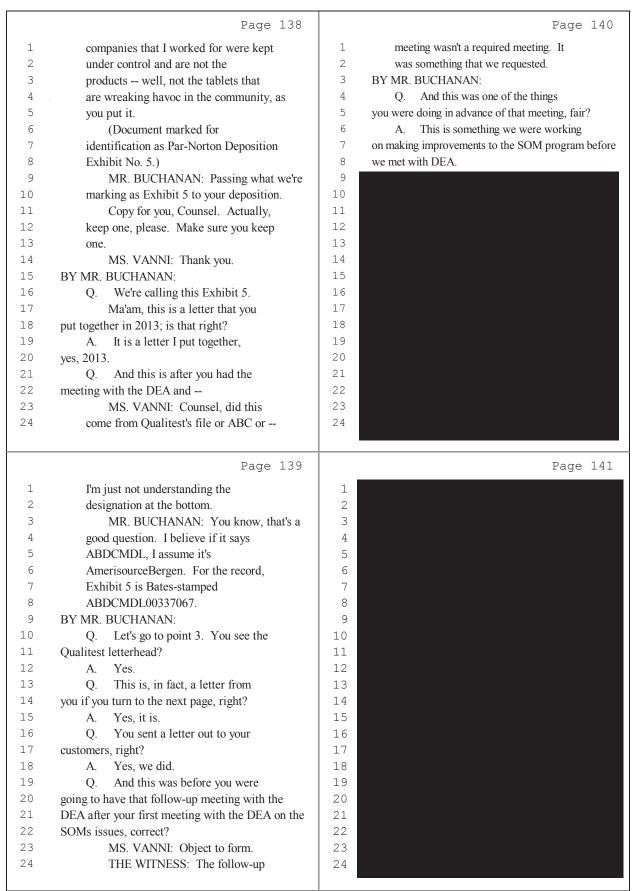
	Page 118		Page 120
1	A. Yes.	1	Q. Who was the head of DEA
2	Q. And there's stories did you go	2	compliance for Endo?
3	and get a Master's in pharmacy?	3	A. There was there were several
4	A. It's a Master's in pharmaceutical	4	people that handled DEA compliance. They didn't
5	policy and regulation.	5	necessarily have that title, from what I can
6	Q. So you learned the regulations,	6	recall.
7	you learned the case law I saw as well in your	7	Q. Did Endo makes controlled
8	resume, right?	8	substances, right?
9	A. Yes, some.	9	A. Endo outsourced controlled
10	Q. And so you saw how the Controlled	10	substances, so they didn't necessarily hold a
11	Substances Act came about, correct?	11	license. They used contract manufacturers, so
12	MS. VANNI: Object to form.	12	the DEA person would really be at that contract
13	THE WITNESS: Yes.	13	manufacturer for the most part.
14	BY MR. BUCHANAN:	14	Q. Am I correct there is no head of
15	Q. You are aware that these drugs	15	DEA compliance for Endo?
16	have been drugs of abuse for a long time, right?	16	MS. VANNI: Objection.
17	MS. VANNI: Objection.	17	THE WITNESS: Not that I knew of.
18	THE WITNESS: The abuse of	18	BY MR. BUCHANAN:
19	controlled substances has changed	19	Q. Okay. If you were looking to
20	drastically over the years, different	20	have a conversation with a counterparty at Endo
21	different products, different entities	21	on DEA compliance issues, there was not a person
22	at different times.	22	like yourself on the other side of the building?
23	BY MR. BUCHANAN:	23	MS. VANNI: Objection.
24	Q. Right.	24	THE WITNESS: Not with that
	<u> </u>		1112 11211255. 1100 11111 1110
	Page 119		Page 121
1	And, for example, back in the	1	title, but the knowledge was there.
2	'70s, there was a drug known as oxymorphone.	2	
3			BY MR. BUCHANAN:
	Have you heard of oxymorphone?	3	
4	Have you heard of oxymorphone? A. Yes.		Q. With who?
4 5	A. Yes.	3	Q. With who?A. Some with Jill Connell, who was
	A. Yes.	3 4	Q. With who? A. Some with Jill Connell, who was my boss when I started. With Sanjay Patel, who
5	A. Yes.Q. Controlled substances?A. Yes.	3 4 5	Q. With who?A. Some with Jill Connell, who was
5 6 7	A. Yes.Q. Controlled substances?A. Yes.Q. Withdrawn from the market?	3 4 5 6 7	Q. With who? A. Some with Jill Connell, who was my boss when I started. With Sanjay Patel, who later came in. With Lisa Walker. Doug Felton was another individual.
5 6 7 8	A. Yes.Q. Controlled substances?A. Yes.Q. Withdrawn from the market?MS. VANNI: Object to form.	3 4 5 6 7 8	Q. With who? A. Some with Jill Connell, who was my boss when I started. With Sanjay Patel, who later came in. With Lisa Walker. Doug Felton was another individual. There was there was just a
5 6 7 8 9	 A. Yes. Q. Controlled substances? A. Yes. Q. Withdrawn from the market? MS. VANNI: Object to form. THE WITNESS: I'm not aware of 	3 4 5 6 7	Q. With who? A. Some with Jill Connell, who was my boss when I started. With Sanjay Patel, who later came in. With Lisa Walker. Doug Felton was another individual. There was there was just a good level of DEA knowledge, I think, at the
5 6 7 8 9	 A. Yes. Q. Controlled substances? A. Yes. Q. Withdrawn from the market? MS. VANNI: Object to form. THE WITNESS: I'm not aware of that. 	3 4 5 6 7 8 9	Q. With who? A. Some with Jill Connell, who was my boss when I started. With Sanjay Patel, who later came in. With Lisa Walker. Doug Felton was another individual. There was there was just a good level of DEA knowledge, I think, at the Endo headquarters from what I experienced.
5 6 7 8 9 10	A. Yes. Q. Controlled substances? A. Yes. Q. Withdrawn from the market? MS. VANNI: Object to form. THE WITNESS: I'm not aware of that. BY MR. BUCHANAN:	3 4 5 6 7 8 9 10	Q. With who? A. Some with Jill Connell, who was my boss when I started. With Sanjay Patel, who later came in. With Lisa Walker. Doug Felton was another individual. There was there was just a good level of DEA knowledge, I think, at the Endo headquarters from what I experienced. Q. So there wasn't a DEA compliance
5 6 7 8 9 10 11	A. Yes. Q. Controlled substances? A. Yes. Q. Withdrawn from the market? MS. VANNI: Object to form. THE WITNESS: I'm not aware of that. BY MR. BUCHANAN: Q. Due to abuse?	3 4 5 6 7 8 9 10 11 12	Q. With who? A. Some with Jill Connell, who was my boss when I started. With Sanjay Patel, who later came in. With Lisa Walker. Doug Felton was another individual. There was there was just a good level of DEA knowledge, I think, at the Endo headquarters from what I experienced. Q. So there wasn't a DEA compliance person, per se, correct?
5 6 7 8 9 10 11 12 13	A. Yes. Q. Controlled substances? A. Yes. Q. Withdrawn from the market? MS. VANNI: Object to form. THE WITNESS: I'm not aware of that. BY MR. BUCHANAN: Q. Due to abuse? Have you heard of numorphan?	3 4 5 6 7 8 9 10 11 12 13	Q. With who? A. Some with Jill Connell, who was my boss when I started. With Sanjay Patel, who later came in. With Lisa Walker. Doug Felton was another individual. There was there was just a good level of DEA knowledge, I think, at the Endo headquarters from what I experienced. Q. So there wasn't a DEA compliance person, per se, correct? MS. VANNI: Object to form.
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5 6 7 8 9 10 11 12 13 14 15 16	A. Yes. Q. Controlled substances? A. Yes. Q. Withdrawn from the market? MS. VANNI: Object to form. THE WITNESS: I'm not aware of that. BY MR. BUCHANAN: Q. Due to abuse? Have you heard of numorphan? A. No. Q. You only when you were at Qualitest, you only had exposure to the generic	3 4 5 6 7 8 9 10 11 12 13 14 15	Q. With who? A. Some with Jill Connell, who was my boss when I started. With Sanjay Patel, who later came in. With Lisa Walker. Doug Felton was another individual. There was there was just a good level of DEA knowledge, I think, at the Endo headquarters from what I experienced. Q. So there wasn't a DEA compliance person, per se, correct? MS. VANNI: Object to form. THE WITNESS: Correct. BY MR. BUCHANAN: Q. In your resume, you talk about
5 6 7 8 9 10 11 12 13 14 15 16 17	A. Yes. Q. Controlled substances? A. Yes. Q. Withdrawn from the market? MS. VANNI: Object to form. THE WITNESS: I'm not aware of that. BY MR. BUCHANAN: Q. Due to abuse? Have you heard of numorphan? A. No. Q. You only when you were at Qualitest, you only had exposure to the generic products, not the branded products?	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. With who? A. Some with Jill Connell, who was my boss when I started. With Sanjay Patel, who later came in. With Lisa Walker. Doug Felton was another individual. There was there was just a good level of DEA knowledge, I think, at the Endo headquarters from what I experienced. Q. So there wasn't a DEA compliance person, per se, correct? MS. VANNI: Object to form. THE WITNESS: Correct. BY MR. BUCHANAN: Q. In your resume, you talk about having to comply with OIG orders and CIAs for
5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Yes. Q. Controlled substances? A. Yes. Q. Withdrawn from the market? MS. VANNI: Object to form. THE WITNESS: I'm not aware of that. BY MR. BUCHANAN: Q. Due to abuse? Have you heard of numorphan? A. No. Q. You only when you were at Qualitest, you only had exposure to the generic products, not the branded products? A. Yes, for the most part.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. With who? A. Some with Jill Connell, who was my boss when I started. With Sanjay Patel, who later came in. With Lisa Walker. Doug Felton was another individual. There was there was just a good level of DEA knowledge, I think, at the Endo headquarters from what I experienced. Q. So there wasn't a DEA compliance person, per se, correct? MS. VANNI: Object to form. THE WITNESS: Correct. BY MR. BUCHANAN: Q. In your resume, you talk about having to comply with OIG orders and CIAs for other manufacturers.
5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Yes. Q. Controlled substances? A. Yes. Q. Withdrawn from the market? MS. VANNI: Object to form. THE WITNESS: I'm not aware of that. BY MR. BUCHANAN: Q. Due to abuse? Have you heard of numorphan? A. No. Q. You only when you were at Qualitest, you only had exposure to the generic products, not the branded products? A. Yes, for the most part. Q. Okay. If I understand, your silo	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. With who? A. Some with Jill Connell, who was my boss when I started. With Sanjay Patel, who later came in. With Lisa Walker. Doug Felton was another individual. There was there was just a good level of DEA knowledge, I think, at the Endo headquarters from what I experienced. Q. So there wasn't a DEA compliance person, per se, correct? MS. VANNI: Object to form. THE WITNESS: Correct. BY MR. BUCHANAN: Q. In your resume, you talk about having to comply with OIG orders and CIAs for other manufacturers. During your time at Qualitest,
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. Yes. Q. Controlled substances? A. Yes. Q. Withdrawn from the market? MS. VANNI: Object to form. THE WITNESS: I'm not aware of that. BY MR. BUCHANAN: Q. Due to abuse? Have you heard of numorphan? A. No. Q. You only when you were at Qualitest, you only had exposure to the generic products, not the branded products? A. Yes, for the most part. Q. Okay. If I understand, your silo of responsibilities with regard to DEA	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. With who? A. Some with Jill Connell, who was my boss when I started. With Sanjay Patel, who later came in. With Lisa Walker. Doug Felton was another individual. There was there was just a good level of DEA knowledge, I think, at the Endo headquarters from what I experienced. Q. So there wasn't a DEA compliance person, per se, correct? MS. VANNI: Object to form. THE WITNESS: Correct. BY MR. BUCHANAN: Q. In your resume, you talk about having to comply with OIG orders and CIAs for other manufacturers. During your time at Qualitest, were there any CIAs or other orders, regulatory
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yes. Q. Controlled substances? A. Yes. Q. Withdrawn from the market? MS. VANNI: Object to form. THE WITNESS: I'm not aware of that. BY MR. BUCHANAN: Q. Due to abuse? Have you heard of numorphan? A. No. Q. You only when you were at Qualitest, you only had exposure to the generic products, not the branded products? A. Yes, for the most part. Q. Okay. If I understand, your silo of responsibilities with regard to DEA compliance was strictly on the Qualitest side?	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. With who? A. Some with Jill Connell, who was my boss when I started. With Sanjay Patel, who later came in. With Lisa Walker. Doug Felton was another individual. There was there was just a good level of DEA knowledge, I think, at the Endo headquarters from what I experienced. Q. So there wasn't a DEA compliance person, per se, correct? MS. VANNI: Object to form. THE WITNESS: Correct. BY MR. BUCHANAN: Q. In your resume, you talk about having to comply with OIG orders and CIAs for other manufacturers. During your time at Qualitest, were there any CIAs or other orders, regulatory orders that you were charged with enforcing?
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes. Q. Controlled substances? A. Yes. Q. Withdrawn from the market? MS. VANNI: Object to form. THE WITNESS: I'm not aware of that. BY MR. BUCHANAN: Q. Due to abuse? Have you heard of numorphan? A. No. Q. You only when you were at Qualitest, you only had exposure to the generic products, not the branded products? A. Yes, for the most part. Q. Okay. If I understand, your silo of responsibilities with regard to DEA compliance was strictly on the Qualitest side? A. I would be consulted occasionally	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. With who? A. Some with Jill Connell, who was my boss when I started. With Sanjay Patel, who later came in. With Lisa Walker. Doug Felton was another individual. There was there was just a good level of DEA knowledge, I think, at the Endo headquarters from what I experienced. Q. So there wasn't a DEA compliance person, per se, correct? MS. VANNI: Object to form. THE WITNESS: Correct. BY MR. BUCHANAN: Q. In your resume, you talk about having to comply with OIG orders and CIAs for other manufacturers. During your time at Qualitest, were there any CIAs or other orders, regulatory orders that you were charged with enforcing? A. I'm sorry, CIAs?
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yes. Q. Controlled substances? A. Yes. Q. Withdrawn from the market? MS. VANNI: Object to form. THE WITNESS: I'm not aware of that. BY MR. BUCHANAN: Q. Due to abuse? Have you heard of numorphan? A. No. Q. You only when you were at Qualitest, you only had exposure to the generic products, not the branded products? A. Yes, for the most part. Q. Okay. If I understand, your silo of responsibilities with regard to DEA compliance was strictly on the Qualitest side?	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. With who? A. Some with Jill Connell, who was my boss when I started. With Sanjay Patel, who later came in. With Lisa Walker. Doug Felton was another individual. There was there was just a good level of DEA knowledge, I think, at the Endo headquarters from what I experienced. Q. So there wasn't a DEA compliance person, per se, correct? MS. VANNI: Object to form. THE WITNESS: Correct. BY MR. BUCHANAN: Q. In your resume, you talk about having to comply with OIG orders and CIAs for other manufacturers. During your time at Qualitest, were there any CIAs or other orders, regulatory orders that you were charged with enforcing?

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1	company committed to do things in a certain way.	1	Yours should be as well.
2	A. No.	2	BY MR. BUCHANAN:
3	Q. Okay. From a compliance	3	Q. Do you have two pages, ma'am?
4	perspective at Qualitest, your compliance was	4	A. Yes.
5	focused on the regulatory framework, the	5	Q. So on the screen, we see a chart,
6	statutory framework and, if you will, the	6	and this chart was prepared by our office from
7	industry framework, correct?	7	the spreadsheets that are referenced here and
8	MS. VANNI: Object to form.	8	using the data that your counsel has pointed us
9	THE WITNESS: Yes.	9	to, to reflect the shipping data for Par
10	BY MR. BUCHANAN:	10	products.
11	Q. Okay. All right. So let's just	11	Qualitest was ultimately I'm
12	kind of put a fine point on Qualitest's	12	sorry, Par was ultimately acquired by Endo, and
13	business.	13	the Qualitest business went into Par.
14	(Document marked for	14	Do you have that understanding?
15	identification as Par-Norton Deposition	15	A. Yes.
16	Exhibit No. 4.)	16	Q. Okay. All right. So this is
17	BY MR. BUCHANAN:	17	looking back in time, and there's a list of
18	Q. Passing you what's been marked as	18	products on the left.
19	Exhibit 4. It's 1157.	19	Do you see those?
20	MR. BUCHANAN: Bradley, if you	20	A. Yes, I do.
21	could pull it up.	21	Q. Okay. Some of these are
22	MS. VANNI: Do you have a copy	22	controlled substances and CS2, some are CS3,
23	for me?	23	some are Schedule I, right?
24	MR. BUCHANAN: Oh, I'm sorry.	24	A. There are no Schedule I.
	Page 123		Page 125
1	MS. VANNI: Thank you.	1	Q. Oh, I don't see that would be
2	MR. BUCHANAN: I need one back,	2	what, pseudoephedrine-type products?
3	actually. Keep that in the folder.	3	A. No, a Schedule I drug has no
4	BY MR. BUCHANAN:	4	medical use in the United States. If you are
5	O 1771 11 D 1 11 4		
	Q. We're marking as Exhibit 4 a	5	referring to pseudoephedrine, that's a List I
6	summary of Qualitest shipments.	5 6	referring to pseudoephedrine, that's a List I chemical.
6	summary of Qualitest shipments. MS. VANNI: Counsel, I'm assuming this is produced in native, but could	6	chemical.
6 7 8 9	summary of Qualitest shipments. MS. VANNI: Counsel, I'm assuming this is produced in native, but could you read the Bates number into this.	6 7 8 9	chemical. Q. Thank you. That's what I was trying to convey. And we don't have List I
6 7 8 9 10	summary of Qualitest shipments. MS. VANNI: Counsel, I'm assuming this is produced in native, but could you read the Bates number into this. MR. BUCHANAN: Yeah, the Bates	6 7 8 9 10	chemical. Q. Thank you. That's what I was trying to convey. And we don't have List I chemicals on here, correct?
6 7 8 9 10 11	summary of Qualitest shipments. MS. VANNI: Counsel, I'm assuming this is produced in native, but could you read the Bates number into this. MR. BUCHANAN: Yeah, the Bates number is so this we've asked you	6 7 8 9	chemical. Q. Thank you. That's what I was trying to convey. And we don't have List I chemicals on here, correct? A. Correct.
6 7 8 9 10 11	summary of Qualitest shipments. MS. VANNI: Counsel, I'm assuming this is produced in native, but could you read the Bates number into this. MR. BUCHANAN: Yeah, the Bates number is so this we've asked you for your shipping information, and	6 7 8 9 10 11 12	chemical. Q. Thank you. That's what I was trying to convey. And we don't have List I chemicals on here, correct? A. Correct. Q. So these are products. Which of
6 7 8 9 10 11	summary of Qualitest shipments. MS. VANNI: Counsel, I'm assuming this is produced in native, but could you read the Bates number into this. MR. BUCHANAN: Yeah, the Bates number is so this we've asked you for your shipping information, and you've pointed us to this particular	6 7 8 9 10 11	chemical. Q. Thank you. That's what I was trying to convey. And we don't have List I chemicals on here, correct? A. Correct. Q. So these are products. Which of these of Schedule II, ma'am?
6 7 8 9 10 11	summary of Qualitest shipments. MS. VANNI: Counsel, I'm assuming this is produced in native, but could you read the Bates number into this. MR. BUCHANAN: Yeah, the Bates number is so this we've asked you for your shipping information, and you've pointed us to this particular document. I guess I could ask the	6 7 8 9 10 11 12	chemical. Q. Thank you. That's what I was trying to convey. And we don't have List I chemicals on here, correct? A. Correct. Q. So these are products. Which of these of Schedule II, ma'am? A. The Endocet, the Endodan,
6 7 8 9 10 11 12	summary of Qualitest shipments. MS. VANNI: Counsel, I'm assuming this is produced in native, but could you read the Bates number into this. MR. BUCHANAN: Yeah, the Bates number is so this we've asked you for your shipping information, and you've pointed us to this particular document. I guess I could ask the witness to sum it, but that would be a	6 7 8 9 10 11 12 13	chemical. Q. Thank you. That's what I was trying to convey. And we don't have List I chemicals on here, correct? A. Correct. Q. So these are products. Which of these of Schedule II, ma'am?
6 7 8 9 10 11 12 13	summary of Qualitest shipments. MS. VANNI: Counsel, I'm assuming this is produced in native, but could you read the Bates number into this. MR. BUCHANAN: Yeah, the Bates number is so this we've asked you for your shipping information, and you've pointed us to this particular document. I guess I could ask the witness to sum it, but that would be a poor use of our day together, but the	6 7 8 9 10 11 12 13 14	chemical. Q. Thank you. That's what I was trying to convey. And we don't have List I chemicals on here, correct? A. Correct. Q. So these are products. Which of these of Schedule II, ma'am? A. The Endocet, the Endodan, hydrocodone products, ibudone I believe is Schedule II. Some of the ones in the middle,
6 7 8 9 10 11 12 13 14	summary of Qualitest shipments. MS. VANNI: Counsel, I'm assuming this is produced in native, but could you read the Bates number into this. MR. BUCHANAN: Yeah, the Bates number is so this we've asked you for your shipping information, and you've pointed us to this particular document. I guess I could ask the witness to sum it, but that would be a poor use of our day together, but the Bates numbers at the top Par Opioid	6 7 8 9 10 11 12 13 14 15	chemical. Q. Thank you. That's what I was trying to convey. And we don't have List I chemicals on here, correct? A. Correct. Q. So these are products. Which of these of Schedule II, ma'am? A. The Endocet, the Endodan, hydrocodone products, ibudone I believe is
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6 7 8 9 10 11 12 13 14 15 16 17	summary of Qualitest shipments. MS. VANNI: Counsel, I'm assuming this is produced in native, but could you read the Bates number into this. MR. BUCHANAN: Yeah, the Bates number is so this we've asked you for your shipping information, and you've pointed us to this particular document. I guess I could ask the witness to sum it, but that would be a poor use of our day together, but the Bates numbers at the top Par Opioid	6 7 8 9 10 11 12 13 14 15 16 17	chemical. Q. Thank you. That's what I was trying to convey. And we don't have List I chemicals on here, correct? A. Correct. Q. So these are products. Which of these of Schedule II, ma'am? A. The Endocet, the Endodan, hydrocodone products, ibudone I believe is Schedule II. Some of the ones in the middle, Peritab I'm not sure of. Morphine is Schedule
6 7 8 9 10 11 12 13 14 15 16 17	summary of Qualitest shipments. MS. VANNI: Counsel, I'm assuming this is produced in native, but could you read the Bates number into this. MR. BUCHANAN: Yeah, the Bates number is so this we've asked you for your shipping information, and you've pointed us to this particular document. I guess I could ask the witness to sum it, but that would be a poor use of our day together, but the Bates numbers at the top Par Opioid MDL0001596805, Par Opioid	6 7 8 9 10 11 12 13 14 15 16 17	chemical. Q. Thank you. That's what I was trying to convey. And we don't have List I chemicals on here, correct? A. Correct. Q. So these are products. Which of these of Schedule II, ma'am? A. The Endocet, the Endodan, hydrocodone products, ibudone I believe is Schedule II. Some of the ones in the middle, Peritab I'm not sure of. Morphine is Schedule II. Opana is Schedule II. Oxycone,
6 7 8 9 10 11 12 13 14 15 16 17 18	summary of Qualitest shipments. MS. VANNI: Counsel, I'm assuming this is produced in native, but could you read the Bates number into this. MR. BUCHANAN: Yeah, the Bates number is so this we've asked you for your shipping information, and you've pointed us to this particular document. I guess I could ask the witness to sum it, but that would be a poor use of our day together, but the Bates numbers at the top Par Opioid MDL0001596805, Par Opioid MDL00015968013-68019. I believe these	6 7 8 9 10 11 12 13 14 15 16 17 18	chemical. Q. Thank you. That's what I was trying to convey. And we don't have List I chemicals on here, correct? A. Correct. Q. So these are products. Which of these of Schedule II, ma'am? A. The Endocet, the Endodan, hydrocodone products, ibudone I believe is Schedule II. Some of the ones in the middle, Peritab I'm not sure of. Morphine is Schedule II. Opana is Schedule II. Oxycone, oxymorphone, Percocet most of them are
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	summary of Qualitest shipments. MS. VANNI: Counsel, I'm assuming this is produced in native, but could you read the Bates number into this. MR. BUCHANAN: Yeah, the Bates number is so this we've asked you for your shipping information, and you've pointed us to this particular document. I guess I could ask the witness to sum it, but that would be a poor use of our day together, but the Bates numbers at the top Par Opioid MDL0001596805, Par Opioid MDL00015968013-68019. I believe these are spreadsheets that you have produced	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	chemical. Q. Thank you. That's what I was trying to convey. And we don't have List I chemicals on here, correct? A. Correct. Q. So these are products. Which of these of Schedule II, ma'am? A. The Endocet, the Endodan, hydrocodone products, ibudone I believe is Schedule II. Some of the ones in the middle, Peritab I'm not sure of. Morphine is Schedule II. Opana is Schedule II. Oxycone, oxymorphone, Percocet most of them are Schedule II.
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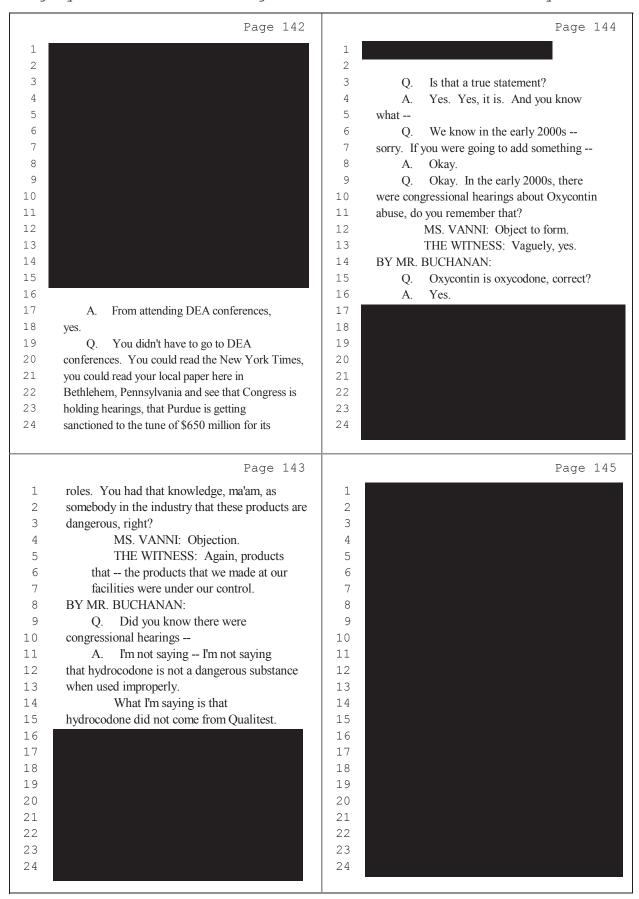
	Page 126		Page 128
1	products by year. I guess if we looked over	1	MS. VANNI: Object to form.
2	time and we only have data going back to	2	THE WITNESS: It appears that
3	2008, we don't have it past 2015.	3	way.
4	So if we looked at oxycodone, for	4	BY MR. BUCHANAN:
5	example, and you told us before that was	5	Q. Can we agree that's a lot?
6	Oxycontin, right? That's the active	6	MS. VANNI: Objection.
7	pharmaceutical ingredient?	7	THE WITNESS: It depends on the
8	A. In the brand, in the brand.	8	scenario. I don't know what's a lot
9	Q. In branded form, it's Oxycontin,	9	versus a little. It's not something
10	correct?	10	that I was involved in or
11	A. Mm-hmm.	11	BY MR. BUCHANAN:
12	Q. So, you know, roughly 2.8, 2.9,	12	Q. I mean, close to ten pills for
13	is that million pills or billion pills, ma'am?	13	every human being in the United States
14	2.8 million?	14	MS. VANNI: Objection.
15	A. Yes.	15	BY MR. BUCHANAN
16	Q. It's billion, right?	16	Q over a seven-year period of
17	MS. VANNI: Where are you	17	time
18	looking?	18	MS. VANNI: Objection.
19	THE WITNESS: The total.	19	THE WITNESS: Mm-hmm.
20	BY MR. BUCHANAN:	20	BY MR. BUCHANAN:
21	Q. 2.8 billion pills?	21	Q does that qualify as a lot to
22	A. Mm-hmm.	22	you
23	Q. Wow. That's a lot.	23	MS. VANNI: Objection.
24	MS. VANNI: Object to form.	24	BY MR. BUCHANAN:
	,		
	Page 127		Page 129
		1	
1	BY MR. BUCHANAN:	1	Q from one manufacturer?
1 2	Q. Could we agree?	1 2	Q from one manufacturer?MS. VANNI: Objection.
2	Q. Could we agree?	2	MS. VANNI: Objection.
2	Q. Could we agree?MS. VANNI: Objection.	2 3	MS. VANNI: Objection. THE WITNESS: I can't make that
2 3 4	Q. Could we agree?MS. VANNI: Objection.THE WITNESS: I don't know the	2 3 4	MS. VANNI: Objection. THE WITNESS: I can't make that determination.
2 3 4 5	Q. Could we agree? MS. VANNI: Objection. THE WITNESS: I don't know the data that I'm looking at, I'm not sure	2 3 4 5	MS. VANNI: Objection. THE WITNESS: I can't make that determination. BY MR. BUCHANAN:
2 3 4 5 6	Q. Could we agree? MS. VANNI: Objection. THE WITNESS: I don't know the data that I'm looking at, I'm not sure where it's coming from. And when you're	2 3 4 5 6	MS. VANNI: Objection. THE WITNESS: I can't make that determination. BY MR. BUCHANAN: Q. Okay. And that's just one, one
2 3 4 5 6 7	Q. Could we agree? MS. VANNI: Objection. THE WITNESS: I don't know the data that I'm looking at, I'm not sure where it's coming from. And when you're talking shipments so a shipment in	2 3 4 5 6 7	MS. VANNI: Objection. THE WITNESS: I can't make that determination. BY MR. BUCHANAN: Q. Okay. And that's just one, one item on this sheet.
2 3 4 5 6 7 8	Q. Could we agree? MS. VANNI: Objection. THE WITNESS: I don't know the data that I'm looking at, I'm not sure where it's coming from. And when you're talking shipments so a shipment in DEA's mind could be a transfer from one	2 3 4 5 6 7 8	MS. VANNI: Objection. THE WITNESS: I can't make that determination. BY MR. BUCHANAN: Q. Okay. And that's just one, one item on this sheet. We've got oxycodone APAP
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2 3 4 5 6 7 8 9	Q. Could we agree? MS. VANNI: Objection. THE WITNESS: I don't know the data that I'm looking at, I'm not sure where it's coming from. And when you're talking shipments so a shipment in DEA's mind could be a transfer from one location to another. It's not necessarily a sale to a customer. I	2 3 4 5 6 7 8 9	MS. VANNI: Objection. THE WITNESS: I can't make that determination. BY MR. BUCHANAN: Q. Okay. And that's just one, one item on this sheet. We've got oxycodone APAP combinations. That's 533 million, right? A. Yes.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. Could we agree? MS. VANNI: Objection. THE WITNESS: I don't know the data that I'm looking at, I'm not sure where it's coming from. And when you're talking shipments so a shipment in DEA's mind could be a transfer from one location to another. It's not necessarily a sale to a customer. I don't know which facility this is referring to, which and, you know, whether it's big or small is opinion. So BY MR. BUCHANAN Q. Okay. And we could fuss with the data. That would probably require me to fuss	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	MS. VANNI: Objection. THE WITNESS: I can't make that determination. BY MR. BUCHANAN: Q. Okay. And that's just one, one item on this sheet. We've got oxycodone APAP combinations. That's 533 million, right? A. Yes. Q. They're up to 3.3, 3.4 billion pills of Oxycontin or Oxycontin combinations. How about you talked about Vicodin before, you said that's a schedule drug, right? A. Yes. Q. Do you see the generic equivalent of Vicodin on this sheet, ma'am?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Q. Could we agree? MS. VANNI: Objection. THE WITNESS: I don't know the data that I'm looking at, I'm not sure where it's coming from. And when you're talking shipments so a shipment in DEA's mind could be a transfer from one location to another. It's not necessarily a sale to a customer. I don't know which facility this is referring to, which and, you know, whether it's big or small is opinion. So BY MR. BUCHANAN Q. Okay. And we could fuss with the data. That would probably require me to fuss with your counsel because this is what they've pointed us to for the sales of the product. A. Mm-hmm.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	MS. VANNI: Objection. THE WITNESS: I can't make that determination. BY MR. BUCHANAN: Q. Okay. And that's just one, one item on this sheet. We've got oxycodone APAP combinations. That's 533 million, right? A. Yes. Q. They're up to 3.3, 3.4 billion pills of Oxycontin or Oxycontin combinations. How about you talked about Vicodin before, you said that's a schedule drug, right? A. Yes. Q. Do you see the generic equivalent of Vicodin on this sheet, ma'am? A. The Hydrocodone product?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. Could we agree? MS. VANNI: Objection. THE WITNESS: I don't know the data that I'm looking at, I'm not sure where it's coming from. And when you're talking shipments so a shipment in DEA's mind could be a transfer from one location to another. It's not necessarily a sale to a customer. I don't know which facility this is referring to, which and, you know, whether it's big or small is opinion. So BY MR. BUCHANAN Q. Okay. And we could fuss with the data. That would probably require me to fuss with your counsel because this is what they've pointed us to for the sales of the product. A. Mm-hmm. Q. Let's just talk about a number, I	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	MS. VANNI: Objection. THE WITNESS: I can't make that determination. BY MR. BUCHANAN: Q. Okay. And that's just one, one item on this sheet. We've got oxycodone APAP combinations. That's 533 million, right? A. Yes. Q. They're up to 3.3, 3.4 billion pills of Oxycontin or Oxycontin combinations. How about you talked about Vicodin before, you said that's a schedule drug, right? A. Yes. Q. Do you see the generic equivalent of Vicodin on this sheet, ma'am? A. The Hydrocodone product? Q. Okay. Let's look up there. MR. BUCHANAN: Can you highlight
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Could we agree? MS. VANNI: Objection. THE WITNESS: I don't know the data that I'm looking at, I'm not sure where it's coming from. And when you're talking shipments so a shipment in DEA's mind could be a transfer from one location to another. It's not necessarily a sale to a customer. I don't know which facility this is referring to, which and, you know, whether it's big or small is opinion. So BY MR. BUCHANAN Q. Okay. And we could fuss with the data. That would probably require me to fuss with your counsel because this is what they've pointed us to for the sales of the product. A. Mm-hmm.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MS. VANNI: Objection. THE WITNESS: I can't make that determination. BY MR. BUCHANAN: Q. Okay. And that's just one, one item on this sheet. We've got oxycodone APAP combinations. That's 533 million, right? A. Yes. Q. They're up to 3.3, 3.4 billion pills of Oxycontin or Oxycontin combinations. How about you talked about Vicodin before, you said that's a schedule drug, right? A. Yes. Q. Do you see the generic equivalent of Vicodin on this sheet, ma'am? A. The Hydrocodone product? Q. Okay. Let's look up there.

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Page 130
                                                                                                   Page 132
                                                            1
                                                                           Am I doing my math right, ma'am?
 1
        That's 33 billion. 33 billion pills, right?
        33 billion Vicodins Qualitest made and shipped
                                                            2
 2
                                                                           MS. VANNI: Object to form.
 3
        between 2008 and 2015?
                                                            3
                                                                  BY MR. BUCHANAN:
                MS. VANNI: Objection.
                                                            4
 4
                                                                       Q. Does that look right to you, 25,
 5
                 THE WITNESS: Again, I don't -- I
                                                            5
                                                                  $26 billion in just Vicodin?
                                                            6
            can't comment on this data. There's not
                                                                           MS. VANNI: Object to the form.
 6
 7
            enough information here. I don't know
                                                            7
                                                                  BY MR. BUCHANAN:
                                                                       Q. Right?
 8
            what the background is. I don't know
                                                            8
                                                            9
 9
            what's a lot and what's a small amount.
                                                                       A. Again, can't comment on the
10
            I mean, I'm not a physician, I'm not one
                                                          10
                                                                  financials. I didn't get involved with the
11
            to make a determination of small versus
                                                          11
                                                                  financials.
12
                                                          12
                                                                           I mean, does this help clarify
            large.
        BY MR. BUCHANAN:
13
                                                          13
                                                                  for you, ma'am, this is actually sale and
            Q. A hundred Vicodin for every human
14
                                                          14
                                                                  shipping data?
15
        being of every age in the United States?
                                                          15
                                                                           MS. VANNI: Object to form.
                 MS. VANNI: Objection.
                                                                           THE WITNESS: No, because a sale
16
                                                          16
17
        BY MR. BUCHANAN:
                                                          17
                                                                       is also a transfer. When you're -- when
18
                                                          18
                                                                       you're talking about a movement from a
            Q. Is that a lot to you?
19
            A. I don't know.
                                                                       distributor, you know, I don't know
                                                          19
20
                 MS. VANNI: Objection.
                                                          20
                                                                       whether this is a movement from
21
        BY MR. BUCHANAN:
                                                          21
                                                                       Qualitest distribution to a storage
22
            Q. Well, when you were the head of
                                                          22
                                                                       location, if it's a movement from a
23
        DEA compliance for Qualitest, did you have the
                                                          23
                                                                       manufacturer to a distributor. I don't
        sense, ma'am, that -- this company was pumping
24
                                                          24
                                                                       have any -- and even if I did, I can't
                                         Page 131
                                                                                                   Page 133
 1
        out controlled substances at this rate?
                                                           1
                                                                      comment on whether that amount is large,
                                                           2
 2
                 MS. VANNI: Objection.
                                                                      small. Not something that I dealt with.
 3
                 THE WITNESS: We were a large
                                                            3
                                                                      I don't have anything to compare it to,
                                                            4
                                                                      in other words.
 4
             manufacturer and distributor of
                                                            5
                                                                  BY MR. BUCHANAN:
 5
             controlled products. I'm sure there
 6
             were larger.
                                                            6
                                                                      Q. Okay. I mean, did you have the
 7
                                                            7
        BY MR. BUCHANAN:
                                                                  sense, though, ma'am, that the company during
 8
                                                           8
                                                                  your tenure was pumping out billions and
             Q. There's other people -- somebody
                                                           9
 9
        made -- this is just you, right? This is just
                                                                  billions and billions of Vicodin every year?
                                                          10
10
        one manufacturer, Qualitest, right?
                                                                          MS. VANNI: Objection.
                                                          11
11
             A. And again --
                                                                          THE WITNESS: The company was an
12
                 MS. VANNI: Object to form.
                                                          12
                                                                      ongoing manufacturer of controlled
                 THE WITNESS: -- you don't know
                                                          13
13
                                                                      substances.
14
             whether these are sales, whether these
                                                          14
                                                                  BY MR. BUCHANAN:
                                                          15
15
             are shipments for transfer. This is not
                                                                      Q. Okay. And so very important, if
                                                          16
                                                                  you're manufacturing enough Vicodin to give
16
             conclusive.
17
                                                          17
                                                                  every human being, living person in the United
        BY MR. BUCHANAN:
18
             Q. Well, so if we go to the next
                                                          18
                                                                  States 100 pills from just your manufacturing
19
        sheet, the company gave us the dollars and the
                                                          19
                                                                  facility, very important if you're that type of
        sales for these; do you see that?
                                                          20
                                                                  manufacturer to make sure you are maintaining a
20
21
                                                          21
                                                                  closed system with effective controls against
             A.
                  Mm-hmm.
22
                  And they're telling us, if you
                                                          22
                                                                  diversion, true?
                                                          23
23
        highlight those two hydrocodone lines, what is
                                                                          MS. VANNI: Objection.
24
        that, looks like about $25 billion in sales.
                                                          24
                                                                          THE WITNESS: Any -- any
```

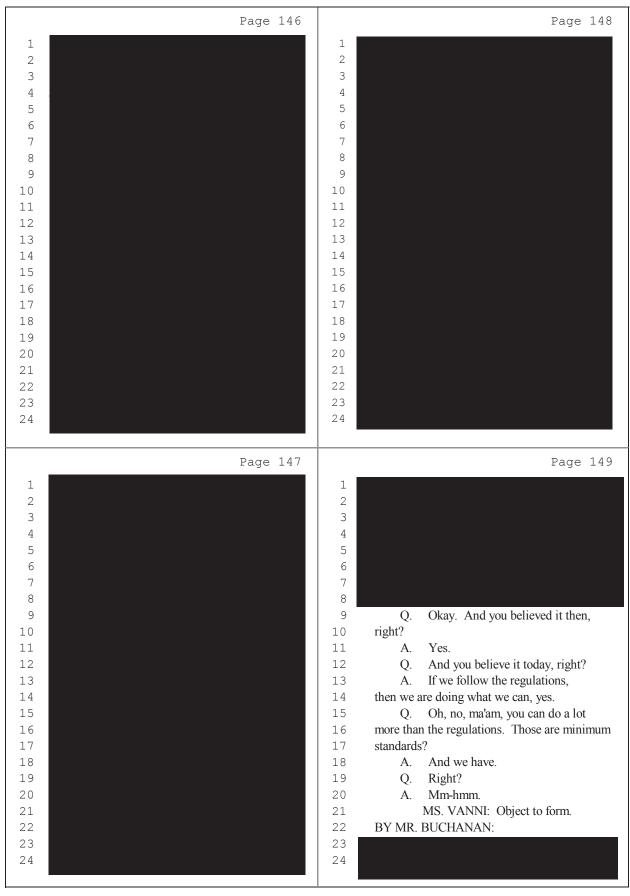
	Page 134		Page 136
1	controlled substance manufacturer, it's	1	BY MR. BUCHANAN:
2	important.	2	Q. Make sure it's only getting to
3	BY MR. BUCHANAN:	3	customers who are getting it for legitimate
4	Q. That's right. Top to bottom, if	4	purposes, right?
5	you're making a million, a million pills can	5	A. Yes.
6	cause a lot of problems, right?	6	Q. Make sure that your customers
7	MS. VANNI: Objection.	7	have processes in place so that they're using it
8	THE WITNESS: If they make it out	8	only for legitimate purposes, right?
9	of the legitimate channel.	9	A. To the best of your ability, yes.
10	BY MR. BUCHANAN:	10	Q. So that you maintain this closed
11	Q. Right.	11	system of distribution because we know at some
12	I mean, if you're just a small	12	point in time, it's not going to be in a safe,
13	manufacturer, you still have to keep this stuff	13	right?
14	in a vault, right?	14	MS. VANNI: Object to form.
15	A. Schedule I and II, yes.	15	THE WITNESS: At the pharmacy
16	MS. VANNI: Objection.	16	level, at the physician yes.
17	BY MR. BUCHANAN:	17	BY MR. BUCHANAN:
18	Q. Schedule II, we're talking about	18	Q. And, ultimately, these are drugs
19	hydrocodone, right?	19	that cause lots of problems, right?
20	A. Yes.	20	MS. VANNI: Object to form.
21	Q. Hydrocodone is Schedule II?	21	THE WITNESS: These are drugs
22	A. For part of the part of my	22	that have a legitimate medical purpose
23	time at Qualitest, hydrocodone was Schedule III,	23	and serve a legitimate need when used
24	which would require it to be in a cage, not a	24	properly.
	Page 135		Page 137
1	vault, but that changed.	1	BY MR. BUCHANAN:
2	Q. Right.	2	Q. These are drugs that wreak havoc
3	G .1 .1 1 . 2012 :		
	So that's what, 2013 or so, it	3	in our communities, would you agree?
4	changed schedule from	3 4	in our communities, would you agree? MS. VANNI: Objection.
4	changed schedule from	4	MS. VANNI: Objection.
4 5	changed schedule from A. 2013, 2014. I'm not exactly	4 5	MS. VANNI: Objection. THE WITNESS: No, I would not
4 5 6	changed schedule from A. 2013, 2014. I'm not exactly sure.	4 5 6	MS. VANNI: Objection. THE WITNESS: No, I would not agree.
4 5 6 7	changed schedule from A. 2013, 2014. I'm not exactly sure. Q. Okay. You still had to keep it	4 5 6 7	MS. VANNI: Objection. THE WITNESS: No, I would not agree. BY MR. BUCHANAN: Q. These are drugs that wreak havoc and devastating consequences in our community,
4 5 6 7 8	changed schedule from A. 2013, 2014. I'm not exactly sure. Q. Okay. You still had to keep it in the cage?	4 5 6 7 8	MS. VANNI: Objection. THE WITNESS: No, I would not agree. BY MR. BUCHANAN: Q. These are drugs that wreak havoc
4 5 6 7 8 9	changed schedule from A. 2013, 2014. I'm not exactly sure. Q. Okay. You still had to keep it in the cage? MS. VANNI: Object to form.	4 5 6 7 8 9	MS. VANNI: Objection. THE WITNESS: No, I would not agree. BY MR. BUCHANAN: Q. These are drugs that wreak havoc and devastating consequences in our community,
4 5 6 7 8 9	changed schedule from A. 2013, 2014. I'm not exactly sure. Q. Okay. You still had to keep it in the cage? MS. VANNI: Object to form. THE WITNESS: Yes.	4 5 6 7 8 9	MS. VANNI: Objection. THE WITNESS: No, I would not agree. BY MR. BUCHANAN: Q. These are drugs that wreak havoc and devastating consequences in our community, do you agree, ma'am?
4 5 6 7 8 9 10	changed schedule from A. 2013, 2014. I'm not exactly sure. Q. Okay. You still had to keep it in the cage? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN:	4 5 6 7 8 9 10 11	MS. VANNI: Objection. THE WITNESS: No, I would not agree. BY MR. BUCHANAN: Q. These are drugs that wreak havoc and devastating consequences in our community, do you agree, ma'am? MS. VANNI: Object to form.
4 5 6 7 8 9 10 11	changed schedule from A. 2013, 2014. I'm not exactly sure. Q. Okay. You still had to keep it in the cage? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Schedule II has to be in a vault,	4 5 6 7 8 9 10 11 12	MS. VANNI: Objection. THE WITNESS: No, I would not agree. BY MR. BUCHANAN: Q. These are drugs that wreak havoc and devastating consequences in our community, do you agree, ma'am? MS. VANNI: Object to form. THE WITNESS: The drugs that were
4 5 6 7 8 9 10 11 12 13	changed schedule from A. 2013, 2014. I'm not exactly sure. Q. Okay. You still had to keep it in the cage? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Schedule II has to be in a vault, a safe?	4 5 6 7 8 9 10 11 12 13	MS. VANNI: Objection. THE WITNESS: No, I would not agree. BY MR. BUCHANAN: Q. These are drugs that wreak havoc and devastating consequences in our community, do you agree, ma'am? MS. VANNI: Object to form. THE WITNESS: The drugs that were manufactured at companies that I worked
4 5 6 7 8 9 10 11 12 13 14	changed schedule from A. 2013, 2014. I'm not exactly sure. Q. Okay. You still had to keep it in the cage? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Schedule II has to be in a vault, a safe? A. Safe for small quantities, yes.	4 5 6 7 8 9 10 11 12 13 14	MS. VANNI: Objection. THE WITNESS: No, I would not agree. BY MR. BUCHANAN: Q. These are drugs that wreak havoc and devastating consequences in our community, do you agree, ma'am? MS. VANNI: Object to form. THE WITNESS: The drugs that were manufactured at companies that I worked for went to legitimate entities.
4 5 6 7 8 9 10 11 12 13 14 15	changed schedule from A. 2013, 2014. I'm not exactly sure. Q. Okay. You still had to keep it in the cage? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Schedule II has to be in a vault, a safe? A. Safe for small quantities, yes. Q. Right. Right.	4 5 6 7 8 9 10 11 12 13 14 15	MS. VANNI: Objection. THE WITNESS: No, I would not agree. BY MR. BUCHANAN: Q. These are drugs that wreak havoc and devastating consequences in our community, do you agree, ma'am? MS. VANNI: Object to form. THE WITNESS: The drugs that were manufactured at companies that I worked for went to legitimate entities. BY MR. BUCHANAN:
4 5 6 7 8 9 10 11 12 13 14 15 16	changed schedule from A. 2013, 2014. I'm not exactly sure. Q. Okay. You still had to keep it in the cage? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Schedule II has to be in a vault, a safe? A. Safe for small quantities, yes. Q. Right. Right. So even if you are a manufacturer	4 5 6 7 8 9 10 11 12 13 14 15 16	MS. VANNI: Objection. THE WITNESS: No, I would not agree. BY MR. BUCHANAN: Q. These are drugs that wreak havoc and devastating consequences in our community, do you agree, ma'am? MS. VANNI: Object to form. THE WITNESS: The drugs that were manufactured at companies that I worked for went to legitimate entities. BY MR. BUCHANAN: Q. Pardon me for a moment.
4 5 6 7 8 9 10 11 12 13 14 15 16 17	changed schedule from A. 2013, 2014. I'm not exactly sure. Q. Okay. You still had to keep it in the cage? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Schedule II has to be in a vault, a safe? A. Safe for small quantities, yes. Q. Right. Right. So even if you are a manufacturer that's not putting out 35 billion pills of Vicodin or selling \$25 billion worth of it,	4 5 6 7 8 9 10 11 12 13 14 15 16	MS. VANNI: Objection. THE WITNESS: No, I would not agree. BY MR. BUCHANAN: Q. These are drugs that wreak havoc and devastating consequences in our community, do you agree, ma'am? MS. VANNI: Object to form. THE WITNESS: The drugs that were manufactured at companies that I worked for went to legitimate entities. BY MR. BUCHANAN: Q. Pardon me for a moment. Is there some debate in your
4 5 6 7 8 9 10 11 12 13 14 15 16 17	changed schedule from A. 2013, 2014. I'm not exactly sure. Q. Okay. You still had to keep it in the cage? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Schedule II has to be in a vault, a safe? A. Safe for small quantities, yes. Q. Right. Right. So even if you are a manufacturer that's not putting out 35 billion pills of Vicodin or selling \$25 billion worth of it, you've got to watch this stuff like a hawk,	4 5 6 7 8 9 10 11 12 13 14 15 16 17	MS. VANNI: Objection. THE WITNESS: No, I would not agree. BY MR. BUCHANAN: Q. These are drugs that wreak havoc and devastating consequences in our community, do you agree, ma'am? MS. VANNI: Object to form. THE WITNESS: The drugs that were manufactured at companies that I worked for went to legitimate entities. BY MR. BUCHANAN: Q. Pardon me for a moment. Is there some debate in your mind, ma'am, as to whether or not these drugs,
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	changed schedule from A. 2013, 2014. I'm not exactly sure. Q. Okay. You still had to keep it in the cage? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Schedule II has to be in a vault, a safe? A. Safe for small quantities, yes. Q. Right. Right. So even if you are a manufacturer that's not putting out 35 billion pills of Vicodin or selling \$25 billion worth of it, you've got to watch this stuff like a hawk, right?	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	MS. VANNI: Objection. THE WITNESS: No, I would not agree. BY MR. BUCHANAN: Q. These are drugs that wreak havoc and devastating consequences in our community, do you agree, ma'am? MS. VANNI: Object to form. THE WITNESS: The drugs that were manufactured at companies that I worked for went to legitimate entities. BY MR. BUCHANAN: Q. Pardon me for a moment. Is there some debate in your mind, ma'am, as to whether or not these drugs, Oxycontin, oxycodone, oxymorphone, hydrocodone
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	changed schedule from A. 2013, 2014. I'm not exactly sure. Q. Okay. You still had to keep it in the cage? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Schedule II has to be in a vault, a safe? A. Safe for small quantities, yes. Q. Right. Right. So even if you are a manufacturer that's not putting out 35 billion pills of Vicodin or selling \$25 billion worth of it, you've got to watch this stuff like a hawk, right? MS. VANNI: Object to form.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	MS. VANNI: Objection. THE WITNESS: No, I would not agree. BY MR. BUCHANAN: Q. These are drugs that wreak havoc and devastating consequences in our community, do you agree, ma'am? MS. VANNI: Object to form. THE WITNESS: The drugs that were manufactured at companies that I worked for went to legitimate entities. BY MR. BUCHANAN: Q. Pardon me for a moment. Is there some debate in your mind, ma'am, as to whether or not these drugs, Oxycontin, oxycodone, oxymorphone, hydrocodone wreak havoc in our communities? MS. VANNI: Object to form.
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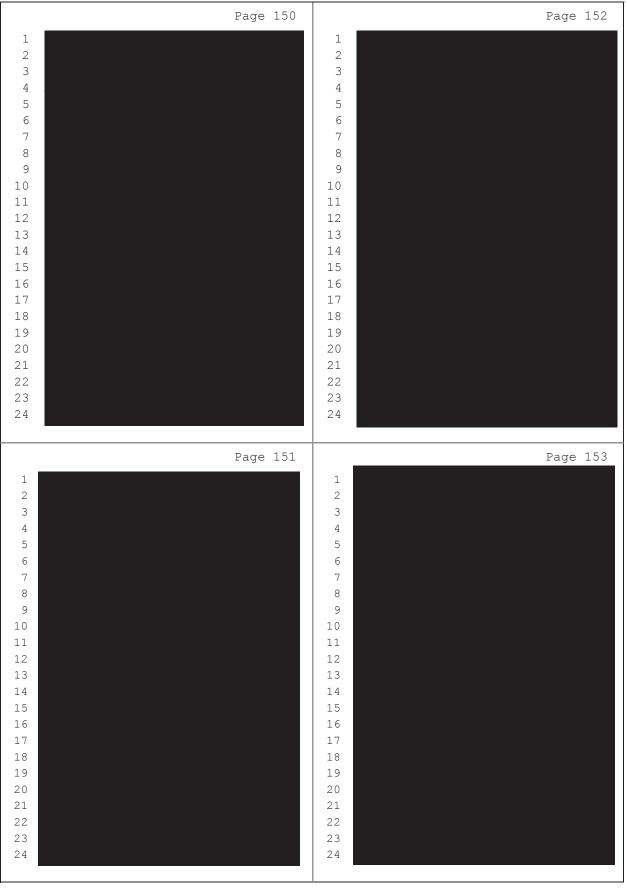
36 (Pages 138 to 141)



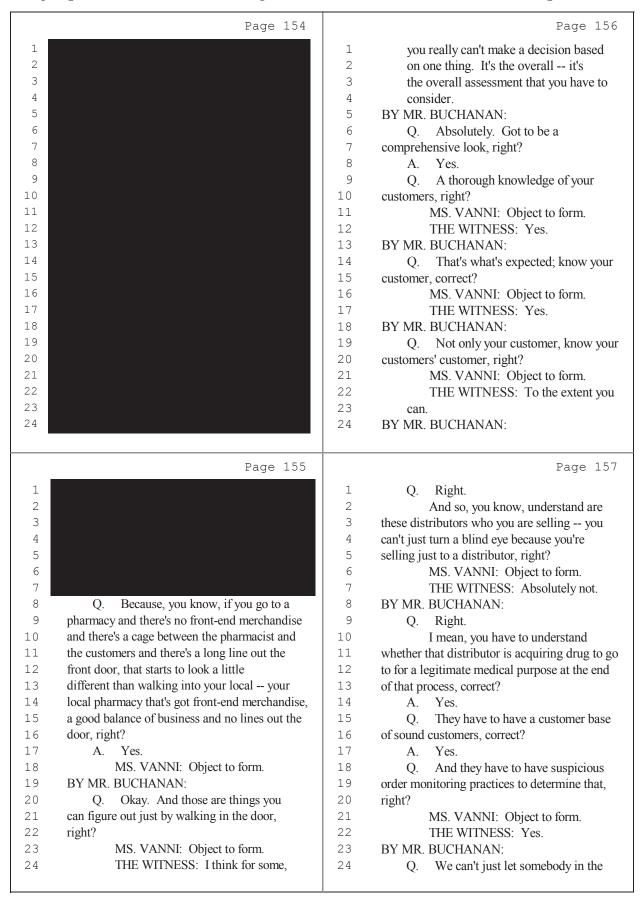
37 (Pages 142 to 145)



38 (Pages 146 to 149)



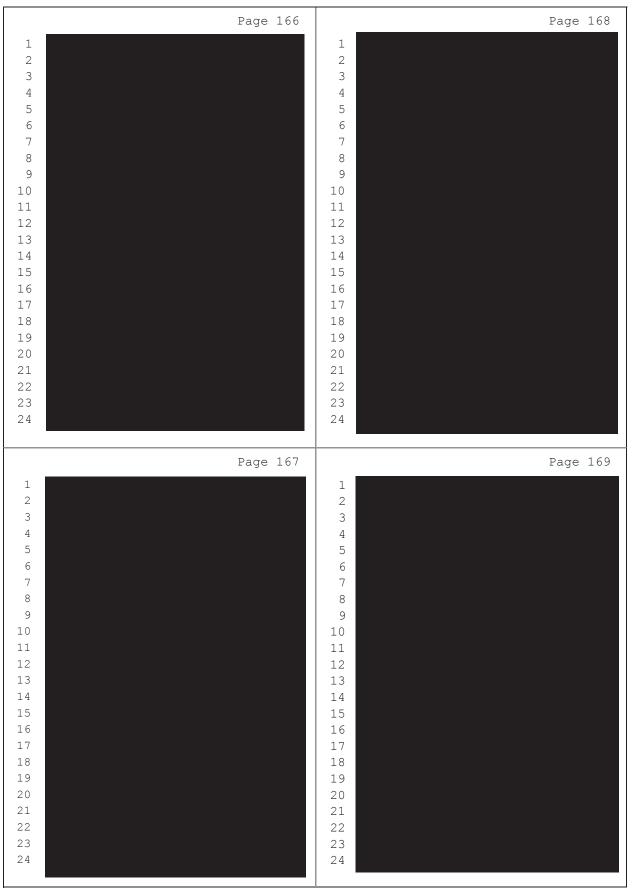
39 (Pages 150 to 153)



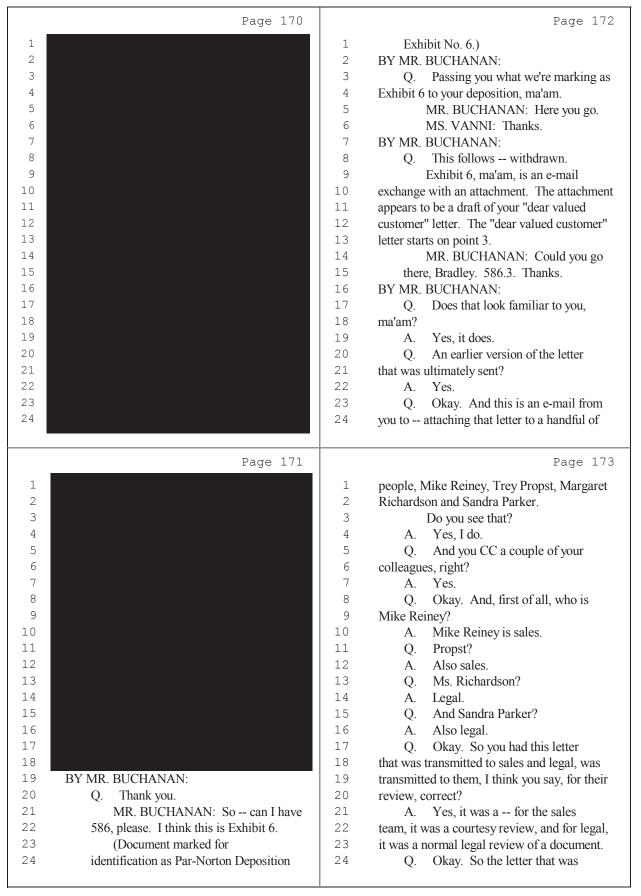
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Page 158
                                                                                                  Page 160
                                                           1
                                                                 of the original regulation or the original SOM
 1
        supply chain put their head in the sand, right?
 2
                                                           2
                                                                 requirements, and they're still not requirements
                 MS. VANNI: Object to form.
 3
                 THE WITNESS: Correct.
                                                           3
                                                                 today.
                                                           4
                                                                      Q. As a manufacturer of 35 billion
 4
        BY MR. BUCHANAN:
 5
                                                           5
                                                                 pills who has got a responsibility to do
            Q. That's very, very dangerous,
                                                                 everything they can to ensure that their product
 6
                                                           6
        right?
 7
                 MS. VANNI: Objection.
                                                           7
                                                                 stays in the appropriate channels, you would
                                                                 agree with me, ma'am, that it is reasonable to
 8
                 THE WITNESS: Potentially, yes.
                                                           8
                                                           9
 9
                                                                 do inspections of your customers, due diligence
        BY MR. BUCHANAN:
10
            Q. We can't have a closed system of
                                                         10
                                                                 visits, correct?
11
        controlled substances if participants in that
                                                         11
                                                                          MS. VANNI: Object to form.
        closed system are going to put their head in the
                                                         12
                                                                          THE WITNESS: In some -- of your
12
13
        sand, correct?
                                                         13
                                                                      direct customers, yes.
14
                                                                 BY MR. BUCHANAN:
                MS. VANNI: Object to form.
                                                         14
15
                THE WITNESS: Yes.
                                                         15
                                                                      Q. It is further reasonable to
                                                                 ensure that your customers are doing the same
16
        BY MR. BUCHANAN:
                                                         16
17
            Q. And so one of your jobs and what
                                                         17
                                                                 thing with their customers, right?
18
        you're saying in this letter is we're no longer
                                                         18
                                                                          MS. VANNI: Object to form.
        going to put our head in the sand, right?
                                                         19
                                                                          THE WITNESS: Not necessarily.
19
20
                                                         20
                 MS. VANNI: Objection.
                                                                 BY MR. BUCHANAN:
21
                THE WITNESS: No, that's not what
                                                         21
                                                                      Q. Okay. When your customers are
                                                                 wholesalers or distributors, you certainly want
22
            we're saying at all.
                                                         22
23
        BY MR. BUCHANAN:
                                                         23
                                                                 to make sure that they've got suspicious order
                                                                 monitoring protocols in place because they've
24
            Q. You are saying we're going to
                                                         24
                                        Page 159
                                                                                                  Page 161
 1
       start doing some due diligence on you, right?
                                                           1
                                                                 got a wide customer base rate?
 2
                MS. VANNI: Objection.
                                                                          MS. VANNI: Object to form.
                                                           2
 3
                THE WITNESS: We are saying we're
                                                           3
                                                                          THE WITNESS: I would want them
                                                                      to have some program. The details of
 4
            making improvements to our existing
                                                           4
 5
                                                           5
                                                                      that program can vary, depending on what
            program.
 6
       BY MR. BUCHANAN:
                                                           6
                                                                      they choose to implement and how
 7
                                                           7
                                                                      effective it is.
            Q. Okay. And we'll talk about what
 8
       the old program looked like versus what the new
                                                           8
                                                                 BY MR. BUCHANAN:
 9
       program looked like. But you are going to start
                                                           9
                                                                           So as a manufacturer, you knew
10
       doing site visits, right?
                                                         10
                                                                 certainly during your time at Qualitest you just
11
                                                                 couldn't ship it to somebody who was going to
            A. Yes.
                                                         11
                                                                 just put their head in the sand, right?
12
                You are going to start seeing
                                                         12
13
       whether they've got lines out the door at the
                                                         13
                                                                          MS. VANNI: Objection.
14
       pharmacies, right?
                                                         14
                                                                          THE WITNESS: Yes.
15
                                                         15
                MS. VANNI: Object to form.
                                                                 BY MR. BUCHANAN:
16
                THE WITNESS: Again, these are
                                                                      Q. You couldn't ship it to somebody
                                                         16
17
            things that DEA --
                                                         17
                                                                 who didn't have suspicious order monitoring
18
       BY MR. BUCHANAN:
                                                         18
                                                                 practices right?
19
                 Could you answer my question
                                                         19
                                                                          MS. VANNI: Objection.
                                                                          THE WITNESS: Yes.
20
       first?
                                                         20
21
                Yes.
                                                         21
                                                                 BY MR. BUCHANAN:
            A.
22
                 Okay.
                                                         22
                                                                         That would be a problem?
            Q.
23
                                                                          MS. VANNI: Objection.
                Again, these are things that DEA
                                                         23
24
       was talking about over time. They were not part
                                                                 BY MR. BUCHANAN:
                                                         2.4
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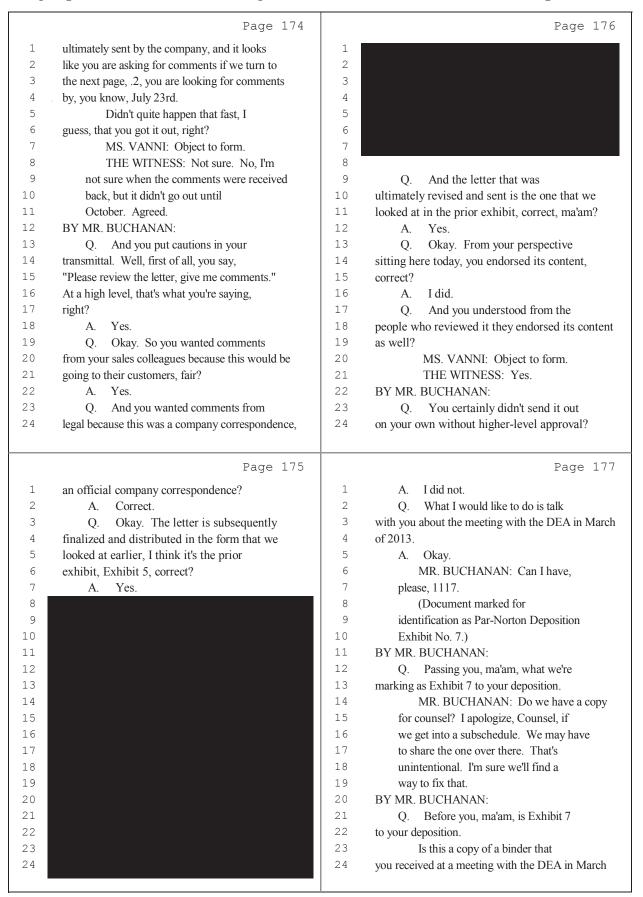
	Page 162		Page 164
1	Q. Not a reason	1	your full customer base, correct?
2	A. It could be, yes.	2	A. Yes.
3	Q. Not a reasonable thing to do,	3	Q. You remember this, right?
4 .	that's for sure, right?	4	A. I do.
5	MS. VANNI: Object to form.	5	Q. It was the responsible and right
6	THE WITNESS: It could be a	6	thing to do, right?
7	problem.	7	A. It was the requirement to
8	BY MR. BUCHANAN:	8	notify not the requirement. It was the
9	Q. And certainly not something a	9	desire to notify the customer that their orders
10	responsible company would do or a responsible	10	might be held and they might be questioned more
11	corporate citizen as you've listed here,	11	than they might be asked to fill out a
12	correct?	12	questionnaire that was different than what they
13	MS. VANNI: Object to form.	13	had filled out in the past.
14	THE WITNESS: Again, the company	14	Q. And you were putting them on
15	is required to abide by the DEA	15	notice that they have a responsibility; they,
16	regulations. That's the only	16	too, have a responsibility
17	obligations of the company. Because I	17	A. Yes.
18	held the company to a different standard	18	Q in this system to do all they
19	is not it's not what's required by	19	can. That's what you told them, right?
20	the company.	20	A. Yes.
21	BY MR. BUCHANAN	21	Q. Does this refresh your
22	Q. What you said, ma'am, was as	22	recollection, though, ma'am, that these drugs
23	responsible corporate citizens, we have a	23	can lead to heart-wrenching problems in our
24	responsibility to do what you set forth in this	24	communities?
	Page 163		Page 165
1	letter, correct?	1	MS. VANNI: Object to form.
2	MS. VANNI: Object to form.	2	THE WITNESS: These drugs
3	THE WITNESS: That is my	3	generally, hydrocodone, oxycodone, yes.
4	individual belief, yes.	4	Again, these drugs did not come from
5	BY MR. BUCHANAN:	5	Qualitest.
6	Q. That was your belief, that was	6	BY MR. BUCHANAN:
7	Qualitest's belief, as reflected in the letter	7	
8	it authorized you to send, correct?	8	
9	MS. VANNI: Object to form.	9	
10	THE WITNESS: Depending on the	10	
11	approvals, yes.	11	
12	BY MR. BUCHANAN:	12	
13	Q. Yeah. I mean, this wasn't	13	
14	some this wasn't some off-the-book thing you	14	
15	did, right?	15	
16	MS. VANNI: Object to form.	16	
17	THE WITNESS: No.	17	
18	BY MR. BUCHANAN:	18	
18	Q. We're not looking at just a side	19	
20	e-mail, you know, my personal view is this,	20	
21	right?	21	
22	MS. VANNI: Object to form.	22	
	DVIAD DIGITATIAN		
23	BY MR. BUCHANAN:	23	
	BY MR. BUCHANAN: Q. This is a letter that went to	23	

42 (Pages 162 to 165)



43 (Pages 166 to 169)





	Page 178		Page 180
1	of 2013?	1	or couldn't?
2	A. Yes, it is.	2	MS. VANNI: Object to form.
3	Q. Okay. We were talking about your	3	THE WITNESS: I don't know.
4	experience at Watson earlier and Anda when you	4	BY MR. BUCHANAN:
5	went in for that meeting.	5	Q. Okay. All right. So this is the
6	A. Yes.	6	binder that you all were given. I guess you
7	Q. Do you recall that?	7	went in you got called in, right?
8	A. I do.	8	MS. VANNI: Object to the form.
9	Q. You had a similar binder when you	9	THE WITNESS: Yes.
10	went in with them?	10	BY MR. BUCHANAN:
11	A. I did.	11	Q. This isn't like they just popped
12	Q. Okay. This was something the DEA	12	into Huntsville, Alabama, right?
13	was doing from time to time with its	13	
14	· ·		A. No.
	registrants, fair?	14	Q. And Huntsville is where you were
15	A. For all distributors, yes.	15	at the time?
16	Q. There are hundreds and hundreds	16	A. Yes, it is.
17	and hundreds of registrants; is that fair?	17	Q. That was the physical location
18	MS. VANNI: Object to form.	18	that you called your office every day when you
19	THE WITNESS: Yes.	19	went to work?
20	BY MR. BUCHANAN:	20	A. Yes.
21	Q. There are hundreds and hundreds	21	Q. DEA compliance had an office
22	of registrant that are distributors, there are	22	DEA compliance or Qualitest had an office in
23	hundreds that are manufacturers, fair?	23	Huntsville?
24	A. Yes.	24	A. Yes, it did, and we also had a
	Page 179		Page 181
1	O. And there's, of course,	1	person in Charlotte.
2	Q. And there's, of course, prescribers	1 2	person in Charlotte. O. Okay. So you get word that
	prescribers	2	Q. Okay. So you get word that
2	prescribers A. Millions of prescribers, yes.	2 3	Q. Okay. So you get word that you're getting called to D.C., right?
2	prescribers A. Millions of prescribers, yes. Q. So but some distributors are	2 3 4	Q. Okay. So you get word that you're getting called to D.C., right? A. Yes.
2 3 4 5	prescribers A. Millions of prescribers, yes. Q. So but some distributors are bigger than others, right?	2 3 4 5	Q. Okay. So you get word that you're getting called to D.C., right? A. Yes. MS. VANNI: Object to form.
2 3 4 5 6	prescribers A. Millions of prescribers, yes. Q. So but some distributors are bigger than others, right? A. Yes.	2 3 4 5 6	Q. Okay. So you get word that you're getting called to D.C., right? A. Yes. MS. VANNI: Object to form. BY MR. BUCHANAN:
2 3 4 5 6 7	prescribers A. Millions of prescribers, yes. Q. So but some distributors are bigger than others, right? A. Yes. Q. Some manufacturers are larger	2 3 4 5 6 7	Q. Okay. So you get word that you're getting called to D.C., right? A. Yes. MS. VANNI: Object to form. BY MR. BUCHANAN: Q. You had a sense of what was
2 3 4 5 6 7 8	prescribers A. Millions of prescribers, yes. Q. So but some distributors are bigger than others, right? A. Yes. Q. Some manufacturers are larger than others?	2 3 4 5 6 7 8	Q. Okay. So you get word that you're getting called to D.C., right? A. Yes. MS. VANNI: Object to form. BY MR. BUCHANAN: Q. You had a sense of what was coming?
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	Page 182		Page 184
1	manufacturer and a distributor, right?	1	A. To a certain extent, yes. Yes.
2	A. Yes.	2	Q. For example, if you go to 1117.4,
3	Q. Had two registrations?	3	they start to tell you about the statute that
4	A. Correct. Well, they had more	4	you operate under, right?
5	more than that. We had lab and import-export,	5	A. Yes.
6	research.	6	Q. The Comprehensive Drug Abuse
7	Q. They had a distributor	7	Prevention and Control Act as amended created a
8	registration and a manufacturer registration?	8	system for the legitimate manufacturing,
9	A. Yes.	9	distribution and prescribing dispensing of
10	Q. Okay. And that's an annual	10	controlled substances.
11	process, you've got to renew that?	11	The next bullet states, "Each
12	A. It is.	12	registrant within the closed system of
13	Q. Okay. And every time you renew	13	distribution has defined privileges and
14	it, you are making a promise you are going to	14	responsibilities in which they must operate."
15	abide by the regulation and the statute with	15	Do you see that?
16	regard to antidiversion, right?	16	A. Yes.
17	MS. VANNI: Objection.	17	Q. And you had that understanding,
18	THE WITNESS: Technically, yes.	18	correct?
19	It's not written on there, but yes.	19	A. I did.
20	BY MR. BUCHANAN:	20	Q. And you didn't need the DEA to
21	Q. That is the that is the	21	tell you that, correct?
22	implied commitment on the part of the	22	A. Not at that point, no.
23	registrants, correct?	23	Q. In fact, you had been working in
24	MS. VANNI: Objection.	24	this framework for 20 years at that point,
	Page 183		Page 185
1			
	THE WITNESS: Yes.	1	right?
2	BY MR. BUCHANAN:	2	A. Yes.
2	BY MR. BUCHANAN: Q. I'm asking for permission to make	2 3	A. Yes.Q. Okay. When a registrant next
2 3 4	BY MR. BUCHANAN: Q. I'm asking for permission to make controlled substances, I will abide by the	2 3 4	A. Yes. Q. Okay. When a registrant next slide, the bottom, "When a registrant fails to
2 3 4 5	BY MR. BUCHANAN: Q. I'm asking for permission to make controlled substances, I will abide by the statute, I will abide by the regulations.	2 3 4 5	A. Yes. Q. Okay. When a registrant next slide, the bottom, "When a registrant fails to adhere to their responsibilities, those
2 3 4 5 6	BY MR. BUCHANAN: Q. I'm asking for permission to make controlled substances, I will abide by the statute, I will abide by the regulations. That's part of the process, correct?	2 3 4 5 6	A. Yes. Q. Okay. When a registrant next slide, the bottom, "When a registrant fails to adhere to their responsibilities, those violations represent a danger to the public and
2 3 4 5 6 7	BY MR. BUCHANAN: Q. I'm asking for permission to make controlled substances, I will abide by the statute, I will abide by the regulations. That's part of the process, correct? MS. VANNI: Object to form.	2 3 4 5 6 7	A. Yes. Q. Okay. When a registrant next slide, the bottom, "When a registrant fails to adhere to their responsibilities, those violations represent a danger to the public and jeopardize the closed system of distribution."
2 3 4 5 6 7 8	BY MR. BUCHANAN: Q. I'm asking for permission to make controlled substances, I will abide by the statute, I will abide by the regulations. That's part of the process, correct? MS. VANNI: Object to form. THE WITNESS: Yes, it is.	2 3 4 5 6 7 8	A. Yes. Q. Okay. When a registrant next slide, the bottom, "When a registrant fails to adhere to their responsibilities, those violations represent a danger to the public and jeopardize the closed system of distribution." Do you see that?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MR. BUCHANAN: Q. I'm asking for permission to make controlled substances, I will abide by the statute, I will abide by the regulations. That's part of the process, correct? MS. VANNI: Object to form. THE WITNESS: Yes, it is. BY MR. BUCHANAN: Q. I would like to direct you to hopefully pages your counsel has. And I guess let's set the table a little bit with what happened that day. So you go up in person, you went with a few other folks from Qualitest? A. I was I believe there was a snowstorm, and we did go with there were other people that were going to be in the room that didn't make it in, but there was at least one other person, I believe, with me.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes. Q. Okay. When a registrant next slide, the bottom, "When a registrant fails to adhere to their responsibilities, those violations represent a danger to the public and jeopardize the closed system of distribution." Do you see that? A. I do. Q. Do you agree with that? A. Yes. Q. And, again, this is on the slide that says closed system, something you understood as of that point in time, correct? A. Yes. Q. And something that you echoed to your customers when you wrote a letter out to them, correct? A. Correct. Q. To the extent others didn't know
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1	MS. VANNI: Object to form.	1	and it elucidates us further with your due
2	THE WITNESS: Yes, that's what I	2	diligence responsibility on E 1117.11. "Due
3	was telling them.	3	diligence" know your customers.
4	BY MR. BUCHANAN:	4	Do you see that?
5	Q. And that's the regulatory	5	A. Yes.
6	framework that we were just talking about, and	6	Q. "Prior to filing an order, the
7	then there's also excuse me, that's the	7	distribute should review the following: Unusual
8	statutory framework, right?	8	frequency of orders, unusual size of orders,
9	A. Mm-hmm.	9	deviating substantially from a normal pattern,"
10	Q. And then we go forward to	10	and then it lists the regulation there.
11	suspicious orders, there's a particular	11	You see that?
12	regulation specific to suspicious orders,	12	A. Yes.
13	correct?	13	Q. And then it continues with due
14	A. 130174.	14	diligence below, "Range of products being
15	Q. Great. We'll go to 1117.9.	15	purchased, methods of payment (cash, insurance,
16	And that regulation requires	16	Medicaid), locations and hours of operation,
17	that and it says "suspicious orders" on the	17	percent controlled versus percent noncontrolled,
18	side. I'm sorry, the one at the bottom.	18	customer pickup at distributorship."
19	MR. BUCHANAN: Thank you,	19	Do you see that?
20	Bradley. Since there's a few documents	20	A. Yes, I do.
21	on the table, I'll try to keep you in	21	Q. "Other aspects of due diligence,"
22	sync.	22	correct?
23	BY MR. BUCHANAN:	23	MS. VANNI: Object to form.
24	Q. The heading on the side is	24	THE WITNESS: Other guidances
	Page 187		D 100
	1 ago 10,		Page 189
1	"Suspicious Orders." The regulation you just	1	from DEA as to what to look at.
1 2		1 2	
	"Suspicious Orders." The regulation you just		from DEA as to what to look at.
2	"Suspicious Orders." The regulation you just stated from memory, ma'am, is listed on the	2	from DEA as to what to look at. BY MR. BUCHANAN:
2	"Suspicious Orders." The regulation you just stated from memory, ma'am, is listed on the slide, right?	2 3	from DEA as to what to look at. BY MR. BUCHANAN: Q. Right.
2 3 4	"Suspicious Orders." The regulation you just stated from memory, ma'am, is listed on the slide, right? A. Yes.	2 3 4	from DEA as to what to look at. BY MR. BUCHANAN: Q. Right. I mean, look, the DEA doesn't
2 3 4 5	"Suspicious Orders." The regulation you just stated from memory, ma'am, is listed on the slide, right? A. Yes. Q. A regulation you've known about	2 3 4 5	from DEA as to what to look at. BY MR. BUCHANAN: Q. Right. I mean, look, the DEA doesn't and the FDA doesn't tell you how to promote your
2 3 4 5 6	"Suspicious Orders." The regulation you just stated from memory, ma'am, is listed on the slide, right? A. Yes. Q. A regulation you've known about for a long time, right?	2 3 4 5 6	from DEA as to what to look at. BY MR. BUCHANAN: Q. Right. I mean, look, the DEA doesn't and the FDA doesn't tell you how to promote your drug to make the most sales, right? Companies
2 3 4 5 6 7	"Suspicious Orders." The regulation you just stated from memory, ma'am, is listed on the slide, right? A. Yes. Q. A regulation you've known about for a long time, right? A. Yes.	2 3 4 5 6 7	from DEA as to what to look at. BY MR. BUCHANAN: Q. Right. I mean, look, the DEA doesn't and the FDA doesn't tell you how to promote your drug to make the most sales, right? Companies figure that out on their own, right?
2 3 4 5 6 7 8	"Suspicious Orders." The regulation you just stated from memory, ma'am, is listed on the slide, right? A. Yes. Q. A regulation you've known about for a long time, right? A. Yes. Q. I mean, you've known about that	2 3 4 5 6 7 8	from DEA as to what to look at. BY MR. BUCHANAN: Q. Right. I mean, look, the DEA doesn't and the FDA doesn't tell you how to promote your drug to make the most sales, right? Companies figure that out on their own, right? MS. VANNI: Object to form.
2 3 4 5 6 7 8 9	"Suspicious Orders." The regulation you just stated from memory, ma'am, is listed on the slide, right? A. Yes. Q. A regulation you've known about for a long time, right? A. Yes. Q. I mean, you've known about that regulation because that's been around since	2 3 4 5 6 7 8	from DEA as to what to look at. BY MR. BUCHANAN: Q. Right. I mean, look, the DEA doesn't and the FDA doesn't tell you how to promote your drug to make the most sales, right? Companies figure that out on their own, right? MS. VANNI: Object to form. THE WITNESS: They do tell you
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2 3 4 5 6 7 8 9 10 11 12	"Suspicious Orders." The regulation you just stated from memory, ma'am, is listed on the slide, right? A. Yes. Q. A regulation you've known about for a long time, right? A. Yes. Q. I mean, you've known about that regulation because that's been around since before your time at Ciba-Geigy? A. Correct. Q. And you've heard about that	2 3 4 5 6 7 8 9 10 11 12	from DEA as to what to look at. BY MR. BUCHANAN: Q. Right. I mean, look, the DEA doesn't and the FDA doesn't tell you how to promote your drug to make the most sales, right? Companies figure that out on their own, right? MS. VANNI: Object to form. THE WITNESS: They do tell you how to promote your drug and how not to promote. BY MR. BUCHANAN:
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	"Suspicious Orders." The regulation you just stated from memory, ma'am, is listed on the slide, right? A. Yes. Q. A regulation you've known about for a long time, right? A. Yes. Q. I mean, you've known about that regulation because that's been around since before your time at Ciba-Geigy? A. Correct. Q. And you've heard about that regulation at distributor conferences and manufacturer conferences, correct? A. Yes. Q. Okay. 21 CFR 1301.74 requires that registrants design and operate a system to identify suspicious orders. Do you see that? A. Yes. Q. "Report suspicious orders to	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	from DEA as to what to look at. BY MR. BUCHANAN: Q. Right. I mean, look, the DEA doesn't and the FDA doesn't tell you how to promote your drug to make the most sales, right? Companies figure that out on their own, right? MS. VANNI: Object to form. THE WITNESS: They do tell you how to promote your drug and how not to promote. BY MR. BUCHANAN: Q. They tell you how you can't do it? A. Yes. Q. I mean, companies are pretty crafty when it comes to figuring out marketing that can be effective, to figure out educational seminars that might educate physicians depending on how you determine the word "educate" and other ways to grow a market for their product.
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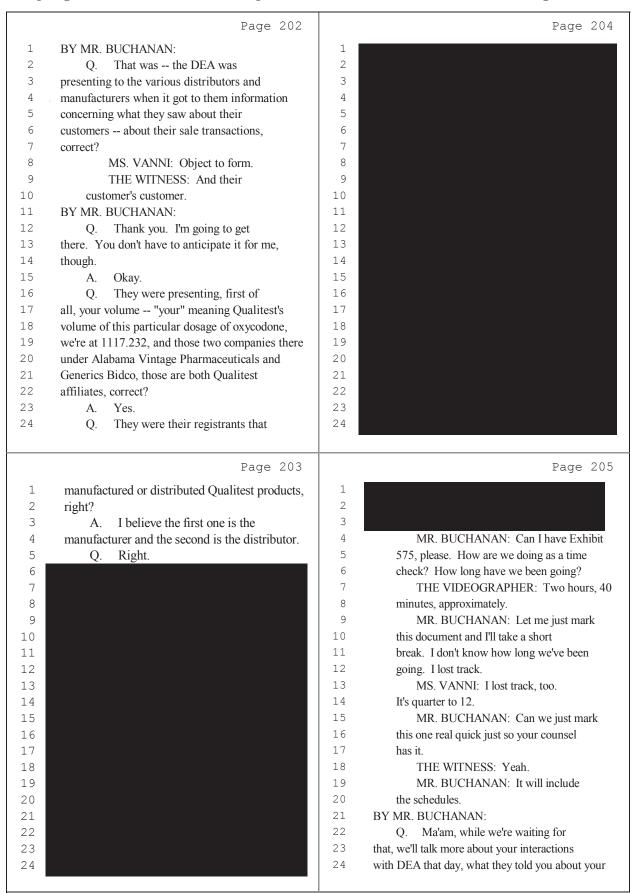
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1	THE WITNESS: Yes, but I think	1	was let go.
2	it's a little bit different.	2	Q. Okay. Two people who had the
3	BY MR. BUCHANAN:	3	title of DEA compliance, or at least under that
4	Q. You agree that as it relates to	4	umbrella, to maintain effective controls against
5	marketing and promotion, companies have	5	diversion?
6	departments built to do that, right?	6	MS. VANNI: Object to form.
7	A. Yes.	7	THE WITNESS: Yes. However, it's
8	Q. Okay. There's also a regulation	8	not it's not just those two people's
9	that says that if you're going to seek our	9	responsibility.
10	permission or a statute that says if you are	10	BY MR. BUCHANAN:
11	going to seek permission to operate in this	11	Q. It should go
12	closed system that you have to have effective	12	A. That's why we train yeah.
13	controls against diversion, right?	13	Q. It should go throughout the
14	A. Yes.	14	organization, that responsibility, right?
15	Q. And companies certainly can, as	15	A. Correct.
16	you have from time to time done, can employ	16	Q. And that was one of the things in
17	their own tools and techniques to maintain	17	2013 after you had this meeting that you set out
18	effective controls against diversion, right?	18	to implement, correct?
19	MS. VANNI: Object to form.	19	A. To enhance.
20	THE WITNESS: Yes.	20	Q. Okay. And we'll talk about what
21	BY MR. BUCHANAN:	21	it was before versus what it was later?
22	Q. There are minimum ways to do it	22	A. Yes.
23	and there's a suspicious order monitoring	23	Q. Because ultimately it's a
24	regulation that says something about that,	24	company-wide obligation to maintain effective
	Page 191		Page 193
1	correct?	1	controls against diversion, correct?
2	correct? A. Correct.	2	controls against diversion, correct? MS. VANNI: Object to form.
2	correct? A. Correct. Q. But ultimately the manufacturers	2	controls against diversion, correct? MS. VANNI: Object to form. THE WITNESS: Just like it's a
2 3 4	correct? A. Correct. Q. But ultimately the manufacturers and distributors have a statutory obligation to	2 3 4	controls against diversion, correct? MS. VANNI: Object to form. THE WITNESS: Just like it's a company-wide obligation to make your
2 3 4 5	correct? A. Correct. Q. But ultimately the manufacturers and distributors have a statutory obligation to maintain effective controls against diversion,	2 3 4 5	controls against diversion, correct? MS. VANNI: Object to form. THE WITNESS: Just like it's a company-wide obligation to make your product safe and effective.
2 3 4 5 6	correct? A. Correct. Q. But ultimately the manufacturers and distributors have a statutory obligation to maintain effective controls against diversion, correct?	2 3 4 5 6	controls against diversion, correct? MS. VANNI: Object to form. THE WITNESS: Just like it's a company-wide obligation to make your product safe and effective. BY MR. BUCHANAN:
2 3 4 5 6 7	correct? A. Correct. Q. But ultimately the manufacturers and distributors have a statutory obligation to maintain effective controls against diversion, correct? MS. VANNI: Object to form.	2 3 4 5 6 7	controls against diversion, correct? MS. VANNI: Object to form. THE WITNESS: Just like it's a company-wide obligation to make your product safe and effective. BY MR. BUCHANAN: Q. Right, right.
2 3 4 5 6 7 8	correct? A. Correct. Q. But ultimately the manufacturers and distributors have a statutory obligation to maintain effective controls against diversion, correct? MS. VANNI: Object to form. THE WITNESS: Yes.	2 3 4 5 6 7 8	controls against diversion, correct? MS. VANNI: Object to form. THE WITNESS: Just like it's a company-wide obligation to make your product safe and effective. BY MR. BUCHANAN: Q. Right, right. Because if you're making
2 3 4 5 6 7 8 9	correct? A. Correct. Q. But ultimately the manufacturers and distributors have a statutory obligation to maintain effective controls against diversion, correct? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN:	2 3 4 5 6 7 8	controls against diversion, correct? MS. VANNI: Object to form. THE WITNESS: Just like it's a company-wide obligation to make your product safe and effective. BY MR. BUCHANAN: Q. Right, right. Because if you're making controlled substances, you've made that
2 3 4 5 6 7 8 9	correct? A. Correct. Q. But ultimately the manufacturers and distributors have a statutory obligation to maintain effective controls against diversion, correct? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Would it be fair to say, ma'am,	2 3 4 5 6 7 8 9	controls against diversion, correct? MS. VANNI: Object to form. THE WITNESS: Just like it's a company-wide obligation to make your product safe and effective. BY MR. BUCHANAN: Q. Right, right. Because if you're making controlled substances, you've made that commitment, you've made that commitment to get
2 3 4 5 6 7 8 9 10	correct? A. Correct. Q. But ultimately the manufacturers and distributors have a statutory obligation to maintain effective controls against diversion, correct? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Would it be fair to say, ma'am, in the time that you've spent at Qualitest, the	2 3 4 5 6 7 8 9 10	controls against diversion, correct? MS. VANNI: Object to form. THE WITNESS: Just like it's a company-wide obligation to make your product safe and effective. BY MR. BUCHANAN: Q. Right, right. Because if you're making controlled substances, you've made that commitment, you've made that commitment to get the permission slip to make the drug that you're
2 3 4 5 6 7 8 9 10 11	A. Correct. Q. But ultimately the manufacturers and distributors have a statutory obligation to maintain effective controls against diversion, correct? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Would it be fair to say, ma'am, in the time that you've spent at Qualitest, the group that handled would you say the	2 3 4 5 6 7 8 9 10 11 12	controls against diversion, correct? MS. VANNI: Object to form. THE WITNESS: Just like it's a company-wide obligation to make your product safe and effective. BY MR. BUCHANAN: Q. Right, right. Because if you're making controlled substances, you've made that commitment, you've made that commitment to get the permission slip to make the drug that you're going to maintain effective controls against
2 3 4 5 6 7 8 9 10 11 12 13	A. Correct. Q. But ultimately the manufacturers and distributors have a statutory obligation to maintain effective controls against diversion, correct? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Would it be fair to say, ma'am, in the time that you've spent at Qualitest, the group that handled would you say the marketing group was bigger than the DEA	2 3 4 5 6 7 8 9 10 11 12 13	controls against diversion, correct? MS. VANNI: Object to form. THE WITNESS: Just like it's a company-wide obligation to make your product safe and effective. BY MR. BUCHANAN: Q. Right, right. Because if you're making controlled substances, you've made that commitment, you've made that commitment to get the permission slip to make the drug that you're going to maintain effective controls against diversion, fair?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Correct. Q. But ultimately the manufacturers and distributors have a statutory obligation to maintain effective controls against diversion, correct? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Would it be fair to say, ma'am, in the time that you've spent at Qualitest, the group that handled would you say the marketing group was bigger than the DEA compliance group? A. Actually, no. Q. The sales group? A. Oh, I don't know. I don't know about out in the field. Maybe, but I don't know. Q. Because in your DEA compliance group before you brought in the people you brought in, when you started there, how many people were in DEA compliance?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	controls against diversion, correct? MS. VANNI: Object to form. THE WITNESS: Just like it's a company-wide obligation to make your product safe and effective. BY MR. BUCHANAN: Q. Right, right. Because if you're making controlled substances, you've made that commitment, you've made that commitment to get the permission slip to make the drug that you're going to maintain effective controls against diversion, fair? A. The quota, yes. MS. VANNI: Object to form. BY MR. BUCHANAN: Q. Right? So as a company, the company must be committed to maintain effective controls against diversion, right? MS. VANNI: Object to form. THE WITNESS: The company can't the individuals at the company
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Correct. Q. But ultimately the manufacturers and distributors have a statutory obligation to maintain effective controls against diversion, correct? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Would it be fair to say, ma'am, in the time that you've spent at Qualitest, the group that handled would you say the marketing group was bigger than the DEA compliance group? A. Actually, no. Q. The sales group? A. Oh, I don't know. I don't know about out in the field. Maybe, but I don't know. Q. Because in your DEA compliance group before you brought in the people you brought in, when you started there, how many	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	controls against diversion, correct? MS. VANNI: Object to form. THE WITNESS: Just like it's a company-wide obligation to make your product safe and effective. BY MR. BUCHANAN: Q. Right, right. Because if you're making controlled substances, you've made that commitment, you've made that commitment to get the permission slip to make the drug that you're going to maintain effective controls against diversion, fair? A. The quota, yes. MS. VANNI: Object to form. BY MR. BUCHANAN: Q. Right? So as a company, the company must be committed to maintain effective controls against diversion, right? MS. VANNI: Object to form. THE WITNESS: The company

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                                         Page 194
                                                            1
 1
            a -- what gets diverted and what doesn't
                                                                        O. Okay. We see the DEA showing
 2
                                                            2
                                                                   examples on 1117.12 of kind of -- it's not the
            or in additional controls that they can
 3
            put in place.
                                                            3
                                                                   best picture, but you've probably seen this
 4
                We learn that from DEA. We learn
                                                            4
                                                                   picture a few times, haven't you?
 5
                                                            5
            that from the guidances and from the
                                                                        A. Yes.
                                                            6
 6
            presentations that they give. We're
                                                                        Q. It's shown up in DEA
 7
            not -- most people in the company are
                                                            7
                                                                   presentations and other presentations?
 8
            not -- they don't have law enforcement
                                                            8
                                                                        A. Yes, it has.
 9
            backgrounds, they don't have medical
                                                            9
                                                                             It's representing really what you
10
            backgrounds.
                                                           10
                                                                   can see when you actually go and see your
11
       BY MR. BUCHANAN:
                                                           11
                                                                   customer, right?
12
            Q. Right.
                                                           12
                                                                            MS. VANNI: Object to form.
13
               So education is an important
                                                           13
                                                                   BY MR. BUCHANAN:
14
       component?
                                                           14
                                                                        Q. Something that you could see in a
15
                It is, from DEA, yes.
                                                           15
                                                                   customer, right?
            A.
16
                Within a company certainly,
                                                           16
                                                                             Potentially.
            Q.
                                                                        A.
17
                                                           17
       right?
                                                                        O.
                                                                            Right, lines --
18
                                                           18
            A.
                Yes.
                                                                             Hopefully not.
                                                                        A.
19
                Within a company, a company has
                                                           19
                                                                             -- people sitting on the floor --
20
                                                           20
       got to educate its employees company-wide on how
                                                                   I mean, would it surprise you to know that you
21
       to maintain effective controls against
                                                           21
                                                                   had customers like this?
22
       diversion, right?
                                                           22
                                                                            MS. VANNI: Object to form.
23
                MS. VANNI: Object to form.
                                                           23
                                                                            THE WITNESS: I would be
               THE WITNESS: To abide by the DEA
24
                                                           24
                                                                        surprised in -- from a Qualitest
                                         Page 195
                                                                                                    Page 197
 1
             regulations, yes.
                                                            1
                                                                        perspective, yes, I would be very
 2
        BY MR. BUCHANAN:
                                                            2
                                                                        surprised.
 3
             Q. And if you're going to -- if
                                                            3
                                                                   BY MR. BUCHANAN:
        you're going to sell controlled substances and
 4
                                                             4
                                                                        Q. Well, Qualitest had direct
        if you are going to make the promise to the
                                                            5
 5
                                                                   pharmacy customers, correct?
 6
        government that you're going to maintain
                                                             6
                                                                            MS. VANNI: Object to form.
 7
                                                            7
        effective controls against the government, you
                                                                   BY MR. BUCHANAN:
 8
                                                            8
        certainly should, right?
                                                                        Q. Do you recall that?
 9
                 MS. VANNI: Object to form.
                                                            9

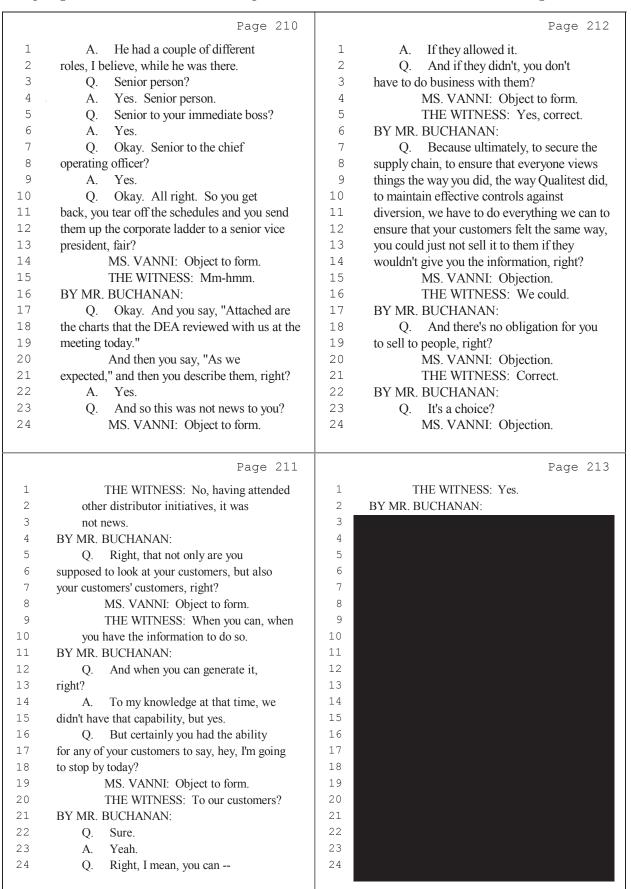
 I don't believe so.

10
                 THE WITNESS: Do training.
                                                           10
                                                                        Q. Okay. Maybe we'll have a chance
11
        BY MR. BUCHANAN:
                                                           11
                                                                   to talk about that at risk of going down too
12
             Q. You certainly -- if you are
                                                           12
                                                                   many different forks in the road to actually get
        saying you are going to maintain effective
                                                           13
                                                                   there, but hopefully we'll have a chance.
13
14
        controls against diversion to get that
                                                           14
                                                                            So these are the types of things
                                                           15
15
        registration, you would agree that you certainly
                                                                   that the DEA is saying to look for. A lot of
        should implement effective controls to prevent
16
                                                           16
                                                                   cash transactions, right? Why could that be a
17
                                                           17
                                                                   sign? Has that been associated with illicit use
        diversion, fair?
18
                                                           18
                 MS. VANNI: Object to form.
                                                                   of drugs?
19
                 THE WITNESS: Yes.
                                                           19
                                                                            That's what DEA says, yes --
20
                                                           20
                                                                            MS. VANNI: Object to form.
        BY MR. BUCHANAN:
21
                                                           21
                                                                            THE WITNESS: There's no
             Q. That's -- that's the promise,
22
                                                           22
        right?
                                                                        traceability.
23
                  Yes, it's a privilege to have a
                                                           23
                                                                   BY MR. BUCHANAN:
             A.
24
                                                           24
        license.
                                                                        Q. Right.
```

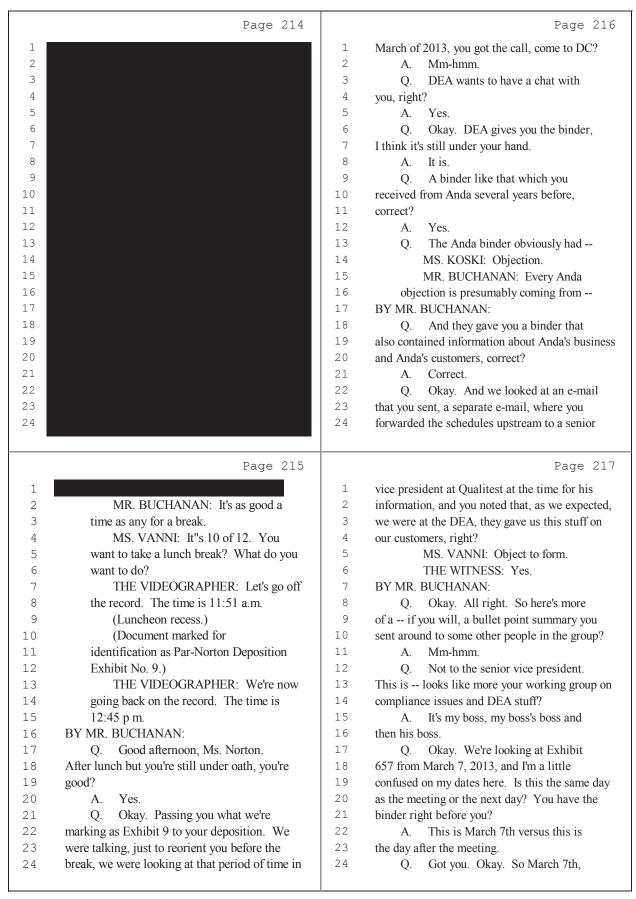
	Page 198		Page 200
1	And, I mean, the use of cash for	1	things like this.
2	drugs was not something that was new in 2011,	2	MR. BUCHANAN: And I'm sorry,
3	right?	3	Counsel, this one is not in yours. I
4	MS. VANNI: Object to form.	4	can see it. We're not going to
5	THE WITNESS: Yeah, should not	5	substantively discuss it.
6	happen.	6	BY MR. BUCHANAN:
7	BY MR. BUCHANAN:	7	Q. They sent you a decision from the
8	Q. No, that shouldn't happen.	8	Supreme Court from 1943, right, Direct Sales
9	That's kind of a commonsense thing, right?	9	versus United States?
10	A. Yes.	10	A. Mm-hmm.
11	Q. If a pharmacy or a customer is	11	Q. And they brought a series of
12	doing, you know, 70, 80% of their business or	12	cases and regulatory actions to your attention
13	50% of their business in controlled substances,	13	about the types of things that are really
14	and the national average is 13%, that might be	14	• • • • • • • • • • • • • • • • • • • •
15			problematic and what you got to be doing and
	something of a red flag, right?	15	what to watch out for, right?
16	A. It would be something	16	MS. VANNI: Object to form.
17	MS. VANNI: Object to form.	17	THE WITNESS: They very much
18	THE WITNESS: to look into	18	skimmed over the cases. They didn't go
19	further, yes.	19	into them in a lot of detail, but they
20	BY MR. BUCHANAN:	20	were presented, yes.
21	Q. Right.	21	BY MR. BUCHANAN:
22	If the pharmacy itself has the	22	Q. Right.
23	cage, no front-end merchandise, that would be	23	And I suppose if you were not a
24	something to consider, right?	24	person who was generally reading that kind of
1	A. It would be.	1	thing, maybe somebody else on your team or maybe
		2	
2	Q. Something that you can see when you go and do the due diligence on your	3	from another manufacturer, they may have found
	, ,		that new and enlightened, but you are saying you
4	customers, right?	4	were aware of this already?
5	A. Yes.	5	MS. VANNI: Object to form.
6	Q. I think you talked about Watson	6	THE WITNESS: Not all of them,
7	actually is a manufacturer starting to implement	7	but some of them, yes.
8	customer visits as part of their SOM program at	8	BY MR. BUCHANAN:
9	your urging, I can't remember whether you were	9	Q. Okay. And then towards the back,
10	instrumental or what word you used in your	10	in kind of more the meat of this is a series of
11	summary, but at your urging, essentially, before	11	charts.
12	you left in 2009, true?	12	Can you pull up so counsel can
13	MS. LEIBELL: Object to form.	13	see it, I don't want to talk about it if she
14	THE WITNESS: We did talk about	14	can't see it, 1117.232. And it's on your screen
15	it obviously, yes.	15	as well, ma'am.
16	BY MR. BUCHANAN:	16	Do you recall the DEA presenting
17	Q. And then we got to the meat of	17	charts like these to you at this meeting in
18	the they sent you a bunch of decisions?	18	2011?
19	A. Yes.	19	A. I do.
20	Q. Probably some that you learned	20	Q. Do you recall the DEA presenting
21	about in your pharmacy classes in Florida,	21	charts like these to you when you were with Anda
22	right?	22	in 2008 or '9?
23	A. And I had a practice of reading	23	A. I do.
-			
24	the Federal Registers or skimming them for	24	MS. KOSKI: Object to form.



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                                                                                                     Page 208
                                                             1
 1
       systems and your self-assessment of the
                                                                   what you told your customers is that as a
 2
       inadequacies in your SOM system at that point in
                                                             2
                                                                   responsible company, you had the obligation to
 3
                                                             3
                                                                   do what was in your letter, and they had the
 4
                                                             4
                                                                   same obligation, that's what you told your
                Do you have a recollection,
 5
       though, that in your eyes, Qualitest SOM
                                                             5
                                                                   customers, right?
 6
       practices at that point in time, as of the time
                                                             6
                                                                        A. The customers, yes. The
 7
       of the DEA meeting, were inadequate?
                                                             7
                                                                   customers needed a heads-up to -- needed
 8
                MS. VANNI: Object to form.
                                                             8
                                                                   education on what was changing.
 9
                                                             9
                THE WITNESS: I would not say
                                                                            (Document marked for
10
            that they were inadequate. I would say
                                                           10
                                                                        identification as Par-Norton Deposition
11
            that we needed to make improvements, and
                                                           11
                                                                        Exhibit No. 8.)
            I would have come back and presented it
                                                           12
12
                                                                             MR. BUCHANAN: I'm passing you,
                                                                        ma'am, what we're marking as Exhibit 8
13
            in a way that -- you know, there's a lot
                                                           13
                                                                        to your deposition. There we go.
14
            going on at a pharmaceutical company and
                                                           14
15
            for -- for this to -- for any
                                                           15
                                                                            MS. VANNI: Thanks.
                                                                   BY MR. BUCHANAN:
16
            improvements that I wanted to make to
                                                           16
            get the right -- to basically -- what --
                                                           17
                                                                        Q. And this is really more for the
17
                                                           18
18
            to get the attention that it needed, you
                                                                   benefit of counsel so they have the charts that
19
            have to make things a little more urgent
                                                           19
                                                                   I was referring to.
20
                                                           20
            than they may actually be, so I'm sure
                                                                             After you got back from the
                                                                   meeting -- this is March 6, 5:58 p m., you tore
21
            you'll see that in my -- in my e-mails.
                                                           21
                                                                   off the schedules and you sent them around
22
       BY MR. BUCHANAN:
                                                           22
23
                                                           23
                                                                   within the company, right?
            Q. Getting management buy-in can be
                                                                            MS. VANNI: Object to form.
24
       a challenge at a pharmaceutical company?
                                                           24
                                         Page 207
                                                                                                     Page 209
 1
                 MS. VANNI: Object to form.
                                                             1
                                                                            THE WITNESS: Yes.
                 THE WITNESS: Not so much -- not
 2
                                                             2
                                                                   BY MR. BUCHANAN:
 3
            so much getting their buy-in, but making
                                                             3
                                                                        Q. And what you're doing is -- who
             them aware of the urgency surrounding
                                                                   is Peter Bigelow, by the way?
 4
                                                             4
 5
            it, that it's not just, you know, Tracey
                                                             5
                                                                        A. He was actually -- at one point,
 6
             wants to make improvements. That
                                                             6
                                                                   he was my supervisor, but he was actually
 7
                                                             7
                                                                   over -- I think he was over Denise and Sanjay at
            there's an impact to making improvements
 8
            and that there's things that -- you
                                                             8
                                                                   the time.
 9
             know, things that we can do better.
                                                             9
                                                                             Senior vice president?
                                                                        Q.
10
        BY MR. BUCHANAN:
                                                           10
                                                                             Sanjay was my supervisor.
                                                                        A.
                                                                             Okay. Senior vice president?
11
            Q. Right.
                                                           11
                                                                        Q.
12
                 I mean, when you're talking about
                                                           12
                                                                             Yes.
                                                                        A.
        controlled substances and the heart-wrenching
                                                           13
                                                                             Yes, okay.
13
                                                                        O.
14
        havoc that they can wreak in the communities,
                                                           14
                                                                            And what was his -- you know,
        responsible companies act to try and minimize
                                                           15
                                                                   senior vice president for sales, drug safety?
15
        that risk by maintaining effective controls
                                                                        A. No.
16
                                                           16
17
        against diversion, you agree?
                                                           17
                                                                            MS. VANNI: Objection.
18
                 MS. VANNI: Object to form.
                                                           18
                                                                            THE WITNESS: He was kind of like
19
                 THE WITNESS: I think the company
                                                           19
                                                                        over the COO, I guess. He was
20
            has to follow the DEA regulations, and
                                                           20
                                                                        contract -- I think he was a contractor
21
            if you do that, then ultimately you will
                                                           21
                                                                        that was brought in, so he was kind of
22
            be preventing that from happening.
                                                           22
                                                                        assisting the plant manager.
        BY MR. BUCHANAN:
                                                                   BY MR. BUCHANAN:
23
                                                           23
24
            Q. And what you wrote certainly and
                                                           24
                                                                        Q. Okay.
```



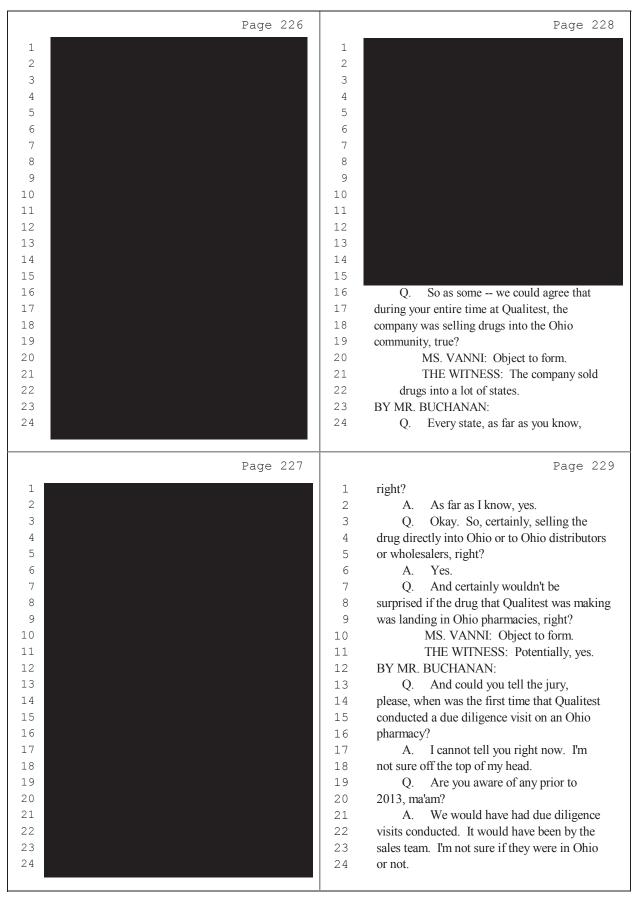
54 (Pages 210 to 213)



Page 220 Page 218 1 1 the next night you're 5:00, I guess late Q. And then what did they say about 2 2 afternoon, you're sending around your notes, and prescription abuse? 3 you note that you were not really in a position 3 "Prescription abuse of these two 4 to be taking the notes yourself. You were kind 4 items is worse than addiction to heroin and 5 5 of doing your best to be engaged with the DEA cocaine." 6 when they were talking to you, right? 6 O. Okay. And that was true, to your 7 A. Yes, to listen. 7 knowledge, at that point in time, right? 8 8 Q. Okay. So this is kind of your MS. VANNI: Object to form. 9 9 notes after you reflected on it and you just had THE WITNESS: That's really 10 a day and you kind of noted down some takeaways, 10 something that I wouldn't know. I was, 11 11 you know, getting that from DEA. 12 MS. VANNI: Object to form. 12 BY MR. BUCHANAN: 13 THE WITNESS: Yes. 13 Q. I mean, you weren't following the 14 14 BY MR. BUCHANAN: public discussion and the congressional hearings 15 Q. Okay. If we scroll down and we 15 and everything that was going on really outside the walls of Qualitest with regard to the looked at a chart of the production of the 16 16 17 17 company's -- I don't know the number of pills, epidemic of opioid abuse? 18 hydrocodone and oxycodone that were made over 18 MS. VANNI: Objection. 19 19 THE WITNESS: I couldn't put a the years. 20 20 Do you recall us looking at that number on it or compare it to heroin or 21 chart earlier today? 21 cocaine without the details coming from A. I recall looking at it, yes. 22 22 DEA. 23 Q. Yeah, and when I say the chart, I 23 BY MR. BUCHANAN: 24 24 mean the one that we generated from the Q. Okay. Suffice it to say, without Page 219 Page 221 1 spreadsheets counsel told us to look at. 1 the DEA telling you that, you still knew it was 2 2 Α Ves a big problem at that point in time? You knew 3 3 there were congressional hearings going on, 4 4 right? 5 5 MS. VANNI: Objection. 6 6 THE WITNESS: I knew that 7 7 hydrocodone and oxycodone was being 8 8 abused. 9 9 BY MR. BUCHANAN: 10 10 that these products, the one identified in the Q. Okay. You knew that they were 11 11 first bullet, hydrocodone and oxycodone products also being diverted, right? 12 are being abused and diverted, right? 12 A. Yes. 13 13 MS. VANNI: Object to form. Q. Okay. They say here 85% of 14 MR. BUCHANAN: Could you 14 oxycodone 30 milligrams sent to Florida is 15 15 highlight, please, the first bullet. diverted, right? 16 16 THE WITNESS: It says DEA is A. That's what DEA told us, yes. 17 looking at top manufacturers of 17 So what's happening is customers, 18 hydrocodone and oxycodone. 18 distributors, wholesalers buying the drug in 19 BY MR. BUCHANAN: 19 Florida or customers of their customers bringing 20 Q. That's right. And then we go to 20 the drug into Florida, that drug is then leaving 21 the third bullet, and they say, "these products 21 Florida and going elsewhere in the country, 22 are being abused and diverted." 22 right? 23 23 Do you see that? MS. VANNI: Object to form. 24 24 THE WITNESS: I don't know if Yes. A.

Page 222 Page 224 1 they were saying it was leaving Florida. 1 people in other countries, right? 2 They were just saying that it was being MS. VANNI: Object to form. 2 3 diverted. It wasn't getting to a 3 THE WITNESS: I don't know if you 4 legitimate channel somewhere down the 4 could make that assumption. 5 5 BY MR. BUCHANAN: line. 6 BY MR. BUCHANAN: 6 You're not aware of that? 7 Q. Fair enough, okay. Got it. So 7 A. No. I'm not. 8 if -- whether it stayed in Florida or whether it 8 O. You're not aware that --9 left Florida, it wasn't landing in the channel 9 I don't have any knowledge of A. 10 where it was supposed to land, right? 10 what goes on in other countries. 11 A. Correct. 11 But as a person engaged in DEA 12 Q. Fair enough, okay. Then it said, compliance, I mean, do you look to see, I mean, 12 the "US uses 90-95% of the hydrocodone produced" what the trends are with regard to the use of 13 13 worldwide. It doesn't say worldwide, but you the products that your manufacturers or 14 14 15 understood that from your meeting, right? 15 distributors are making or distributing? MS. VANNI: Object to form. A. I look at some data, but a lot of 16 16 17 THE WITNESS: Yes. 17 data is not -- not represented well, I don't 18 BY MR. BUCHANAN: 18 think, and it doesn't have the level of detail 19 Q. Okay. So of all of the people in 19 that it needs to accurately focus or address the 20 20 the world with all of their maladies and all of problem. 21 their pain and all of their conditions, this 21 Q. Well then, certainly, you'd want country uses 90 to 95% of all the hydrocodone 22 22 to be really cautious, right? 23 produced in the world, right? 23 MS. VANNI: Object to form. MS. VANNI: Object to form. THE WITNESS: Yes. 24 24 Page 223 Page 225 1 THE WITNESS: That was my 1 BY MR. BUCHANAN: 2 understanding from what they were 2 Q. And you'd be -- want to be really 3 saying, yes. 3 cautious because if we're talking about products that have to be kept in cages or have to be kept 4 BY MR. BUCHANAN: 4 Q. Would it be fair to say, ma'am, 5 in vaults or have to be handled by two people at 5 6 that we don't have 90 to 95% of the world's 6 the same time because we can't really trust one 7 7 population? person or the other not to take this and divert 8 MS. VANNI: Object to form. 8 it, we've got to be really cautious in how we 9 9 THE WITNESS: I'm not sure. I distribute or sell these types of drugs, fair? 10 guess you could say that. I don't know. 10 MS. VANNI: Objection. THE WITNESS: Yes, and we were. 11 I don't know what the population is in 11 12 every country. 12 BY MR. BUCHANAN: BY MR. BUCHANAN: 13 Q. And I move to strike the end. If 13 Q. Well, worldwide, internationally, 14 14 you could stay with my question, ma'am. there are organizations that monitor the use of 15 15 opioids country by country, right? 16 16 17 Mm-hmm. What it tells me is that 17 18 we're more humane in the United States and we 18 19 treat pain as compared to some third world 19 20 countries, for example. 20 21 There's another part of that, 21 22 right? 22 23 Mm-hmm. 23 A. 24 We abuse opioids more than other 24

57 (Pages 222 to 225)



58 (Pages 226 to 229)

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Page 230
                                                                                                     Page 232
 1
            Q. Are you aware of any visits into
                                                            1
                                                                            Right.
        Ohio by the sales team or otherwise prior to
                                                            2
 2
                                                                            So let's -- I just want to
 3
        2013?
                                                             3
                                                                   understand whether these visits by salespeople
            A. I would not know, since I wasn't
                                                             4
                                                                   that may or may not have happened, I mean, was
 4
                                                            5
                                                                   that being done as a formal compliance effort,
 5
        there.
                                                             6
                                                                   where you were generating due diligence files?
 6
            Q. And, frankly, if it happened
 7
        prior to 2013, you're saying I'd have to go talk
                                                            7
                                                                            MS. VANNI: Object to form.
                                                            8
 8
        to a sales rep?
                                                                            THE WITNESS: I can't say if they
 9
                                                            9
            A. Not a sales rep.
                                                                        were or not.
                 MS. VANNI: Object to form.
                                                           10
                                                                   BY MR. BUCHANAN:
10
11
                 THE WITNESS: One of the more --
                                                           11
                                                                       Q. Are you aware of any that
12
                                                           12
                                                                   happened prior to 2013?
            the sales team that would be internal,
13
            not necessarily a sales rep outside.
                                                           13
                                                                       A. I don't know either way.
        BY MR. BUCHANAN:
                                                           14
14
                                                                            Okay. All right. So what the
15
                  Well, certainly, the company and
                                                           15
                                                                   DEA is telling you or at least your takeaway
        its compliance -- this was a compliance function
                                                                   from this meeting in March is, one, you've got
16
                                                           16
17
        you're saying was happening?
                                                           17
                                                                   to get to know your customers, right?
18
                 The visits?
                                                           18
            A.
                                                                       A. Yes.
19
                 Mm-hmm.
                                                           19
                                                                        Q. And they also told you you got to
             O.
20
                                                           20
                                                                   get to know your customers' customers, right?
            A. It was a compliance function
        later, after we -- after we had the personnel
21
                                                           21
                                                                       A. To the extent you can, yes.
                                                                            They told you Ohio is a problem,
22
        and we started doing them.
                                                           22
23
            Q. Okay. Well, I just want to
                                                           23
                                                                   Florida is a problem, right?
        understand the -- kind of the visits you're
                                                           24
                                                                            MS. VANNI: Object to form.
24
                                         Page 231
                                                                                                     Page 233
 1
        saying may have served the same function at
                                                             1
                                                                            THE WITNESS: Yes.
 2
        earlier points in time that you're not sure
                                                             2
                                                                   BY MR. BUCHANAN:
 3
        actually happened in Ohio.
                                                             3
                                                                        Q. You had that knowledge, though,
                 Was that being done as, you know,
                                                                   that Florida today was an issue even before the
 4
                                                             4
        as a know your customer anti-diversion effort;
                                                             5
                                                                   DEA told you, right?
 5
 6
        is that what you're saying?
                                                             6
                                                                        A. Mainly because of seeing it on
 7
                                                             7
                                                                   presentations that they had given, yes.
                 MS. VANNI: Object to the form.
 8
                 THE WITNESS: I really don't
                                                             8
                                                                        Q. Right. I mean, you knew that
 9
             know. I can't comment since I wasn't
                                                             9
                                                                   licenses were getting suspended of
10
                                                           10
                                                                   distributorships and pharmacies were getting
             there.
                                                                   shuttered in -- I shouldn't say shuttered -- the
11
        BY MR. BUCHANAN:
                                                           11
12
             Q. Well, surely if this was being
                                                           12
                                                                   DEA was taking their license, right?
                                                                            MS. VANNI: Object to form.
        done as part of a compliance function, you'd
                                                           13
13
14
        maintain records of due diligence visits like
                                                           14
                                                                            THE WITNESS: Yes.
                                                           15
15
        that, right?
                                                                   BY MR. BUCHANAN:
16
                 MS. VANNI: Object to form.
                                                           16
                                                                        Q. I guess they could continue to
17
                 THE WITNESS: Not necessarily.
                                                           17
                                                                   sell noncontrolled substances and chewing gum
18
             DEA didn't -- they didn't really talk
                                                           18
                                                                   and milk and stuff, but they couldn't sell
19
             about documenting your due diligence
                                                           19
                                                                   controlled substances after that point, right?
20
             until more recent -- you know, not more
                                                           20
                                                                        A.
             recent like this year but, you know,
                                                           21
                                                                             And hefty fines were levied,
21
                                                                        Q.
22
             till later on. As I said, the program,
                                                           22
                                                                   right?
                                                                            MS. VANNI: Object to form.
23
             the SOM program changed over time so...
                                                           23
                                                                            THE WITNESS: Yes.
24
        BY MR. BUCHANAN:
                                                           24
```

Page 234 Page 236 1 BY MR. BUCHANAN: 1 Q. Okay. They then tell you that 2 2 3 "keep a filing system on customers reported to 3 Q. Okay. And so one of the things 4 DEA and a database on due diligence." 4 you could do is you could look through IMS data 5 Do you see that? 5 or you could look through prescription level 6 That's --6 data if you got it through questionnaires or 7 Q. Database on due diligence? 7 through dispensing histories from pharmacies or 8 8 A. Yes, that's exactly where they you could get it from your distributor customers 9 started talking about writing, documenting your 9 if they provided it to you, you could see the 10 due diligence. 10 relative balance of controlled substances versus 11 Q. And we'll look at some of your 11 noncontrolled substances, right? 12 earlier documents that precede this meeting. I 12 MS. VANNI: Object to form. mean, you knew about the DEA's know your 13 13 THE WITNESS: Absolutely not. So customer initiative well before March of 2013, 14 14 as a manufacturer, we were not entitled 15 didn't you, ma'am? 15 to dispensing data, for one. We would MS. VANNI: Object to form. 16 16 not be getting dispensing data. It 17 THE WITNESS: Prior to this 17 would be a HIPAA violation if it wasn't 18 18 meeting, I'm sure it was mentioned at cleansed from patient information for 19 conferences, know your customer. 19 one. 20 20 BY MR. BUCHANAN: BY MR. BUCHANAN: 21 Q. Right. And this, as you said, as 21 Q. Okay. Maybe my question was 22 expected, and the other e-mail and then you 22 confusing then. 23 described what happened at the meeting. 23 And we'll look at this, provided Do you recall that? 24 24 I still have time, the company after it Page 235 Page 237 1 1 A. I do. implemented its revised SOMS actually requested 2 2 Q. Yes. So what's happening here, from its customers and from some of its 3 and I guess you got some visibility in the 3 customers' customers dispensing data that showed 4 charts as to your customers' customers and what 4 aggregate purchases of controlled substances 5 their transactions were? 5 versus noncontrolled substances, correct? 6 6 A. Yes. MS. VANNI: Object to form. 7 7 But you were aware that the DEA THE WITNESS: I don't know 8 had a know your customer expectation before this 8 after -- I'm not sure. I don't believe 9 9 meeting, right? SO 10 10 MS. VANNI: Object to form. BY MR. BUCHANAN: Q. While you were there it happened. 11 11 THE WITNESS: Yes. 12 BY MR. BUCHANAN: 12 Do you recall that? 13 13 A. I recall looking at IMS data for 14 14 the national averages. I don't recall actually 15 15 getting dispensing data. 16 16 Q. Okay. We'll see if we can fill 17 17 in that -- your memory on that if we have time. 18 18 A. Okay. 19 19 Q. But one of the things you can do, 20 20 obviously, is you can see is this pharmacy 21 21 behaving like a pharmacy. Is it purchasing 22 22 roughly 13 to 15% controlled substances, or is 23 23 it doing something different? Is it buying 30, 24 24 40, 50%, right?

	Page 238		Page 240
1	MS. VANNI: Object to form.	1	not rare that you have choice?
2	THE WITNESS: Yes, and it's a	2	MS. VANNI: Object to form.
3	guidance.	3	THE WITNESS: No, I'm saying it's
4	BY MR. BUCHANAN:	4	rare that a customer would not cooperate
5	Q. Right, because it could be that	5	but
6	there's a unique circumstance for that	6	BY MR. BUCHANAN:
7	particular pharmacy. It might be a small one.	7	Q. Right, right. So we will see
8	It might have a particular reason why it's 16%	8	some examples. You recall some customers who
9	rather than 13%, whatever the numbers are?	9	didn't cooperate?
10	A. Correct.	10	A. Yes.
11	Q. So you've got to think, right?	11	O. Some distributors who didn't
12	MS. VANNI: Object to form.	12	cooperate, right?
13	THE WITNESS: Yes.	13	MS. VANNI: Objection.
14	BY MR. BUCHANAN:	14	THE WITNESS: I don't believe so,
		15	but
15	Q. So you get red flags well,	16	BY MR. BUCHANAN:
16	let's take a step back.		
17	The process, as I understand it	17	Q. Some distributors who didn't give
18	is, one, we should get information, right;	18	you their SOM information or had no SOM program.
19	that's what you're being told?	19	Do you recall that?
20	A. Yes.	20	MS. VANNI: Objection.
21	Q. As a participant in this closed	21	THE WITNESS: I do not.
22	system, you have an obligation to get	22	BY MR. BUCHANAN:
23	information on your customers, correct?	23	Q. Because that would be a concern,
24	MS. VANNI: Object to form.	24	right, if it
1	THE WITNESS: Correct	1	_
1 2	THE WITNESS: Correct. BY MR. BUCHANAN:	1 2	A. Yes.
2	BY MR. BUCHANAN:	2	A. Yes.Q. Somebody you were selling drug to
2	BY MR. BUCHANAN: Q. And you have an obligation to get	2 3	A. Yes. Q. Somebody you were selling drug to didn't have a SOM program, right?
2 3 4	BY MR. BUCHANAN: Q. And you have an obligation to get information on your customers' customers, right?	2 3 4	A. Yes. Q. Somebody you were selling drug to didn't have a SOM program, right? MS. VANNI: Objection.
2 3 4 5	BY MR. BUCHANAN: Q. And you have an obligation to get information on your customers' customers, right? MS. VANNI: Object to form.	2 3 4 5	A. Yes. Q. Somebody you were selling drug to didn't have a SOM program, right? MS. VANNI: Objection. BY MR. BUCHANAN:
2 3 4 5 6	BY MR. BUCHANAN: Q. And you have an obligation to get information on your customers' customers, right? MS. VANNI: Object to form. THE WITNESS: To the extent you	2 3 4 5 6	A. Yes. Q. Somebody you were selling drug to didn't have a SOM program, right? MS. VANNI: Objection. BY MR. BUCHANAN: Q. When I say "SOM," I mean a
2 3 4 5 6 7	BY MR. BUCHANAN: Q. And you have an obligation to get information on your customers' customers, right? MS. VANNI: Object to form. THE WITNESS: To the extent you can, yes.	2 3 4 5 6 7	A. Yes. Q. Somebody you were selling drug to didn't have a SOM program, right? MS. VANNI: Objection. BY MR. BUCHANAN: Q. When I say "SOM," I mean a distributor.
2 3 4 5 6 7 8	BY MR. BUCHANAN: Q. And you have an obligation to get information on your customers' customers, right? MS. VANNI: Object to form. THE WITNESS: To the extent you can, yes. BY MR. BUCHANAN:	2 3 4 5 6 7 8	A. Yes. Q. Somebody you were selling drug to didn't have a SOM program, right? MS. VANNI: Objection. BY MR. BUCHANAN: Q. When I say "SOM," I mean a distributor. A. It would depend on controls they
2 3 4 5 6 7 8	BY MR. BUCHANAN: Q. And you have an obligation to get information on your customers' customers, right? MS. VANNI: Object to form. THE WITNESS: To the extent you can, yes. BY MR. BUCHANAN: Q. Right. And so, look, you could	2 3 4 5 6 7 8	A. Yes. Q. Somebody you were selling drug to didn't have a SOM program, right? MS. VANNI: Objection. BY MR. BUCHANAN: Q. When I say "SOM," I mean a distributor. A. It would depend on controls they have in place, other controls that maybe
2 3 4 5 6 7 8 9	BY MR. BUCHANAN: Q. And you have an obligation to get information on your customers' customers, right? MS. VANNI: Object to form. THE WITNESS: To the extent you can, yes. BY MR. BUCHANAN: Q. Right. And so, look, you could have difficult customers who don't cooperate,	2 3 4 5 6 7 8 9	A. Yes. Q. Somebody you were selling drug to didn't have a SOM program, right? MS. VANNI: Objection. BY MR. BUCHANAN: Q. When I say "SOM," I mean a distributor. A. It would depend on controls they have in place, other controls that — maybe they're not calling it a SOMS program, but they
2 3 4 5 6 7 8 9 10	BY MR. BUCHANAN: Q. And you have an obligation to get information on your customers' customers, right? MS. VANNI: Object to form. THE WITNESS: To the extent you can, yes. BY MR. BUCHANAN: Q. Right. And so, look, you could have difficult customers who don't cooperate, that's one thing, correct?	2 3 4 5 6 7 8 9 10	A. Yes. Q. Somebody you were selling drug to didn't have a SOM program, right? MS. VANNI: Objection. BY MR. BUCHANAN: Q. When I say "SOM," I mean a distributor. A. It would depend on controls they have in place, other controls that — maybe they're not calling it a SOMS program, but they have some things in place. It depends on the
2 3 4 5 6 7 8 9 10 11	BY MR. BUCHANAN: Q. And you have an obligation to get information on your customers' customers, right? MS. VANNI: Object to form. THE WITNESS: To the extent you can, yes. BY MR. BUCHANAN: Q. Right. And so, look, you could have difficult customers who don't cooperate, that's one thing, correct? A. Mm-hmm, yes.	2 3 4 5 6 7 8 9 10 11 12	A. Yes. Q. Somebody you were selling drug to didn't have a SOM program, right? MS. VANNI: Objection. BY MR. BUCHANAN: Q. When I say "SOM," I mean a distributor. A. It would depend on controls they have in place, other controls that — maybe they're not calling it a SOMS program, but they have some things in place. It depends on the situation.
2 3 4 5 6 7 8 9 10 11 12 13	BY MR. BUCHANAN: Q. And you have an obligation to get information on your customers' customers, right? MS. VANNI: Object to form. THE WITNESS: To the extent you can, yes. BY MR. BUCHANAN: Q. Right. And so, look, you could have difficult customers who don't cooperate, that's one thing, correct? A. Mm-hmm, yes. Q. And you can choose not to do	2 3 4 5 6 7 8 9 10 11 12 13	A. Yes. Q. Somebody you were selling drug to didn't have a SOM program, right? MS. VANNI: Objection. BY MR. BUCHANAN: Q. When I say "SOM," I mean a distributor. A. It would depend on controls they have in place, other controls that maybe they're not calling it a SOMS program, but they have some things in place. It depends on the situation. Q. Okay. So let's take the let's
2 3 4 5 6 7 8 9 10 11 12 13 14	BY MR. BUCHANAN: Q. And you have an obligation to get information on your customers' customers, right? MS. VANNI: Object to form. THE WITNESS: To the extent you can, yes. BY MR. BUCHANAN: Q. Right. And so, look, you could have difficult customers who don't cooperate, that's one thing, correct? A. Mm-hmm, yes. Q. And you can choose not to do business with them?	2 3 4 5 6 7 8 9 10 11 12 13 14	A. Yes. Q. Somebody you were selling drug to didn't have a SOM program, right? MS. VANNI: Objection. BY MR. BUCHANAN: Q. When I say "SOM," I mean a distributor. A. It would depend on controls they have in place, other controls that maybe they're not calling it a SOMS program, but they have some things in place. It depends on the situation. Q. Okay. So let's take the let's take the name off of it, whether they call it a
2 3 4 5 6 7 8 9 10 11 12 13 14 15	BY MR. BUCHANAN: Q. And you have an obligation to get information on your customers' customers, right? MS. VANNI: Object to form. THE WITNESS: To the extent you can, yes. BY MR. BUCHANAN: Q. Right. And so, look, you could have difficult customers who don't cooperate, that's one thing, correct? A. Mm-hmm, yes. Q. And you can choose not to do business with them? MS. VANNI: Object to form.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. Yes. Q. Somebody you were selling drug to didn't have a SOM program, right? MS. VANNI: Objection. BY MR. BUCHANAN: Q. When I say "SOM," I mean a distributor. A. It would depend on controls they have in place, other controls that maybe they're not calling it a SOMS program, but they have some things in place. It depends on the situation. Q. Okay. So let's take the let's take the name off of it, whether they call it a SOM program. It would be of concern to you,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	BY MR. BUCHANAN: Q. And you have an obligation to get information on your customers' customers, right? MS. VANNI: Object to form. THE WITNESS: To the extent you can, yes. BY MR. BUCHANAN: Q. Right. And so, look, you could have difficult customers who don't cooperate, that's one thing, correct? A. Mm-hmm, yes. Q. And you can choose not to do business with them? MS. VANNI: Object to form. THE WITNESS: Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. Yes. Q. Somebody you were selling drug to didn't have a SOM program, right? MS. VANNI: Objection. BY MR. BUCHANAN: Q. When I say "SOM," I mean a distributor. A. It would depend on controls they have in place, other controls that — maybe they're not calling it a SOMS program, but they have some things in place. It depends on the situation. Q. Okay. So let's take the — let's take the name off of it, whether they call it a SOM program. It would be of concern to you, ma'am, if somebody in this field, if a customer
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	BY MR. BUCHANAN: Q. And you have an obligation to get information on your customers' customers, right? MS. VANNI: Object to form. THE WITNESS: To the extent you can, yes. BY MR. BUCHANAN: Q. Right. And so, look, you could have difficult customers who don't cooperate, that's one thing, correct? A. Mm-hmm, yes. Q. And you can choose not to do business with them? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. Yes. Q. Somebody you were selling drug to didn't have a SOM program, right? MS. VANNI: Objection. BY MR. BUCHANAN: Q. When I say "SOM," I mean a distributor. A. It would depend on controls they have in place, other controls that maybe they're not calling it a SOMS program, but they have some things in place. It depends on the situation. Q. Okay. So let's take the let's take the name off of it, whether they call it a SOM program. It would be of concern to you, ma'am, if somebody in this field, if a customer of a manufacturer, a distributor or a wholesaler
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	Page 242		Page 244
1	after you implemented SOPs at Qualitest,	1	getting back to it, I'm sorry, 657.1, we're
2	correct?	2	going to go to "If we decide to terminate a
3	A. Yes.	3	customer, we should let both the local and HQ
4	Q. That if somebody doesn't give you	4	offices of DEA know."
5	SOM information, we should not be selling to	5	Do you see that?
6	them, right?	6	A. Yes.
7	MS. VANNI: Object to form.	7	Q. Do you agree with that, that's
8	THE WITNESS: Again, depending on	8	something you should do?
9	the scenario, the situation.	9	A. It depends on, again, on the
10	BY MR. BUCHANAN:	10	situation. If we're terminating a customer for
11	Q. Do you recall giving that	11	a for a reason that isn't causing any
12	guidance?	12	diversion or abuse or we don't have a suspicion
13	A. Yes.	13	about that customer, then no there's no reason
14	Q. Because if your customers don't	14	to let DEA know.
15	have SOM programs in place, there can be no	15	Q. Right. I mean, if you're
16	assurance that you're living up to your promise	16	terminating a customer because you believe
17	to get your registration that you're going to	17	they're either a suspicious customer or they've
18	maintain effective controls against diversion,	18	their orders are suspicious, you got to let
19	right?	19	the DEA know, right, no question?
20	MS. VANNI: Object to form.	20	MS. VANNI: Object to form.
21	THE WITNESS: Again, it depends	21	THE WITNESS: The regulation is
22	on the controls that the customer has in	22	you notify them of suspicious orders.
23	place and the situation.	23	It's not the regulation doesn't
24	BY MR. BUCHANAN:	24	require you to notify them if you just
	Page 243		
	rage 243		Page 245
1		1	_
1 2	Q. Well, the controlled system		Page 245 terminate them as a customer. BY MR. BUCHANAN:
	Q. Well, the controlled system doesn't work if you sell it to people who are	2	terminate them as a customer. BY MR. BUCHANAN:
2	Q. Well, the controlled system		terminate them as a customer. BY MR. BUCHANAN: Q. Okay. So these were your high
2	Q. Well, the controlled system doesn't work if you sell it to people who are putting their head in the sand; we can agree on	2 3	terminate them as a customer. BY MR. BUCHANAN:
2 3 4	Q. Well, the controlled system doesn't work if you sell it to people who are putting their head in the sand; we can agree on that? A. Yes.	2 3 4	terminate them as a customer. BY MR. BUCHANAN: Q. Okay. So these were your high level takeaways from the meeting the next day? A. Yes.
2 3 4 5	Q. Well, the controlled system doesn't work if you sell it to people who are putting their head in the sand; we can agree on that?	2 3 4 5	terminate them as a customer. BY MR. BUCHANAN: Q. Okay. So these were your high level takeaways from the meeting the next day? A. Yes. Q. And then I know you implemented a
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Well, the controlled system doesn't work if you sell it to people who are putting their head in the sand; we can agree on that? A. Yes. MS. VANNI: Object to form. BY MR. BUCHANAN: Q. And the system doesn't work if you're selling to people who don't have by name or function suspicious order monitoring programs, correct? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Okay. And suspicious order monitoring programs have been either statutorily or regulatory required for as long as you've been in dealing with controlled substances, correct? A. Yes. Q. And that takes us back to the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	terminate them as a customer. BY MR. BUCHANAN: Q. Okay. So these were your high level takeaways from the meeting the next day? A. Yes. Q. And then I know you implemented a process, and we'll talk about that in a moment, about what you started to do to kind of bring Qualitest SOMS procedures in line, fair? MS. VANNI: Objection to form. THE WITNESS: No, not fair. It was BY MR. BUCHANAN: Q. Okay. We'll see whether it's fair in a moment, so let's pause. (Document marked for identification as Par-Norton Deposition Exhibit No. 10.) MR. BUCHANAN: I'm going to pass you what we're marking it's 1044, Scott next in order is Exhibit 10,

	Page 246		Page 248
1	worked in your organization in compliance?	1	Ms. Boockholdt was at the
2	MS. VANNI: Can I have a copy?	2	meeting?
3	THE WITNESS: Yes.	3	A. I believe so, yes.
4	MR. BUCHANAN: Oh, sorry. It	4	Q. Do you know how to pronounce her
5	should have gone to you first.	5	name?
6	MS. VANNI: Thank you.	6	A. Boockholdt.
7	BY MR. BUCHANAN:	7	Q. Boockholdt, thank you.
8	Q. All right. So Aimee Cooper was	8	And she's with the Office of
9	with you. I guess this is from 2017, but she's	9	Diversion Control, and she's writing to I guess
10	forwarding along in the minutes from the	10	one of her colleagues?
11	March 27 meeting?	11	A. Rannazzisi was in charge of DEA.
12	A. Mm-hmm.	12	Q. And who is he oh, in charge of
13	Q. I'm sorry, not the March 27	13	DEA?
14	meeting. The minutes are stamped March 27,	14	A. Yes.
15	2013.	15	Q. Okay. And he had been talking
16	You see the memorandum on the	16	and writing and speaking about diversion,
17	next page?	17	anti-diversion, suspicious order monitoring for
18	A. Yes.	18	some time, fair?
19	Q. And so what's happening here is I	19	MS. VANNI: Object to form.
20	guess at a later point in time in 2017, there's	20	THE WITNESS: I would assume,
21	a need to look back at the what happened in	21	yes.
22	March of 2013, and they're being forwarded	22	BY MR. BUCHANAN:
23	along.	23	Q. Well, you've been in this space
24	Do you recognize the format of	24	for a while, right?
	Page 247		Page 249
1	the memo that's reflected on page 2?	1	
		1 I	A. Yes.
2		1 2	
2	MS. VANNI: Object to the	2 3	Q. Okay. "Space" meaning suspicious
	MS. VANNI: Object to the colloquy.	2	
3	MS. VANNI: Object to the colloquy. THE WITNESS: I recognize the	2 3	Q. Okay. "Space" meaning suspicious order monitoring, DEA compliance, right?A. Correct.
3 4	MS. VANNI: Object to the colloquy. THE WITNESS: I recognize the format. I'm not sure if I had a copy	2 3 4	Q. Okay. "Space" meaning suspicious order monitoring, DEA compliance, right?A. Correct.Q. You remember in the mid-2000s
3 4 5	MS. VANNI: Object to the colloquy. THE WITNESS: I recognize the	2 3 4 5	Q. Okay. "Space" meaning suspicious order monitoring, DEA compliance, right?A. Correct.
3 4 5 6	MS. VANNI: Object to the colloquy. THE WITNESS: I recognize the format. I'm not sure if I had a copy before I left. This appears to be an	2 3 4 5 6	 Q. Okay. "Space" meaning suspicious order monitoring, DEA compliance, right? A. Correct. Q. You remember in the mid-2000s receiving letters from Mr. Rannazzisi, right?
3 4 5 6 7	MS. VANNI: Object to the colloquy. THE WITNESS: I recognize the format. I'm not sure if I had a copy before I left. This appears to be an internal DEA document.	2 3 4 5 6 7	Q. Okay. "Space" meaning suspicious order monitoring, DEA compliance, right? A. Correct. Q. You remember in the mid-2000s receiving letters from Mr. Rannazzisi, right? MS. VANNI: Object to form.
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	Page 250		Page 252
1	BY MR. BUCHANAN:	1	suspicious order monitoring system."
2	Q. Okay. So let's look at this one.	2	Do you see that, ma'am?
3	This is a recap of the meeting from the	3	A. Yes.
4	perspective of the DEA. Can we scroll down.	4	Q. Okay. And it talks about
5	Probably the second paragraph is where we get	5	Qualitest and its locations and then there's a
6	into the meat of it.	6	sentence attributed to you.
7	Do you see that?	7	Ms. Hernandez was aware of the
8	A. Okay.	8	chargeback system utilized by manufacturers,
9	Q. Okay?	9	including Qualitest, but stating that the firm
10	A. "SC Levin opened."	10	has not reviewed it.
11	Q. SC Levin, do you know SC Levin?	11	Do you see that?
12	A. Yes.	12	A. Yes.
13	Q. What's that C stand for?	13	Q. Do you recall discussing that
14	A. Special staff coordinator.	14	with the DEA?
15	Q. Got you. Staff coordinator	15	A. Yes, I do.
16	Levin, somebody with the DEA?	16	· · · · · · · · · · · · · · · · · · ·
17	A. Yes, headquarters.	17	Q. Okay. And that accurately sets
18	_		forth at least that portion of the discussion,
	The state of the s	18	right?
19 20	this is a summary of, I guess, Barbara	19	A. Yes.
	Boockholdt of what happened at the meeting three	20	Q. Okay. "Ms. Hernandez stated the
21	weeks earlier with you?	21	firm's suspicious order monitoring system is a
22	A. I believe so, yes.	22	work in progress."
23	Q. Okay. SC Levin opened the	23	Do you see that?
24	meeting by stating the purpose was both	24	A. Yes.
	Page 251		D 050
			Page 253
1		1	_
1 2	educational and informative. SC Levin stated he	1 2	Q. "And it is currently based on
2	educational and informative. SC Levin stated he would discuss Qualitest's responsibilities under	2	Q. "And it is currently based on historical purchases by an individual customer
2	educational and informative. SC Levin stated he would discuss Qualitest's responsibilities under the Controlled Substances Act, their suspicious	2 3	Q. "And it is currently based on historical purchases by an individual customer (thresholds)."
2 3 4	educational and informative. SC Levin stated he would discuss Qualitest's responsibilities under the Controlled Substances Act, their suspicious order monitoring system, their procedures	2 3 4	Q. "And it is currently based on historical purchases by an individual customer (thresholds)." Did I read that correctly?
2 3 4 5	educational and informative. SC Levin stated he would discuss Qualitest's responsibilities under the Controlled Substances Act, their suspicious order monitoring system, their procedures concerning due diligence, knowing their	2 3 4 5	Q. "And it is currently based on historical purchases by an individual customer (thresholds)." Did I read that correctly? A. Yes, you did.
2 3 4 5 6	educational and informative. SC Levin stated he would discuss Qualitest's responsibilities under the Controlled Substances Act, their suspicious order monitoring system, their procedures concerning due diligence, knowing their customers, who their customers sell to and	2 3 4 5 6	Q. "And it is currently based on historical purchases by an individual customer (thresholds)." Did I read that correctly? A. Yes, you did. Q. Okay. Stated that you do not
2 3 4 5 6 7	educational and informative. SC Levin stated he would discuss Qualitest's responsibilities under the Controlled Substances Act, their suspicious order monitoring system, their procedures concerning due diligence, knowing their customers, who their customers sell to and graphs depicting the pharmacies and	2 3 4 5 6 7	Q. "And it is currently based on historical purchases by an individual customer (thresholds)." Did I read that correctly? A. Yes, you did. Q. Okay. Stated that you do not routinely visit customers to determine who they
2 3 4 5 6 7 8	educational and informative. SC Levin stated he would discuss Qualitest's responsibilities under the Controlled Substances Act, their suspicious order monitoring system, their procedures concerning due diligence, knowing their customers, who their customers sell to and graphs depicting the pharmacies and practitioners where oxycodone in various	2 3 4 5 6 7 8	Q. "And it is currently based on historical purchases by an individual customer (thresholds)." Did I read that correctly? A. Yes, you did. Q. Okay. Stated that you do not routinely visit customers to determine who they are selling to and "Qualitest does not visit
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	educational and informative. SC Levin stated he would discuss Qualitest's responsibilities under the Controlled Substances Act, their suspicious order monitoring system, their procedures concerning due diligence, knowing their customers, who their customers sell to and graphs depicting the pharmacies and practitioners where oxycodone in various formulations and hydrocodone in various formulations were ultimately dispensed from. Do you see that, ma'am? A. Yes. Q. And as an encapsulation, is that a good high level summary of what happened during the meeting? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Okay. It states that in the next	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. "And it is currently based on historical purchases by an individual customer (thresholds)." Did I read that correctly? A. Yes, you did. Q. Okay. Stated that you do not routinely visit customers to determine who they are selling to and "Qualitest does not visit their pharmacies or practitioners who dispense their product." Do you see that? A. Yes. Q. Do you recall discussing that with the DEA? A. I do. Q. So you don't dispute the characterization of the meeting? A. No. Q. Okay. "Ms. Hernandez stated the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	educational and informative. SC Levin stated he would discuss Qualitest's responsibilities under the Controlled Substances Act, their suspicious order monitoring system, their procedures concerning due diligence, knowing their customers, who their customers sell to and graphs depicting the pharmacies and practitioners where oxycodone in various formulations and hydrocodone in various formulations were ultimately dispensed from. Do you see that, ma'am? A. Yes. Q. And as an encapsulation, is that a good high level summary of what happened during the meeting? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Okay. It states that in the next paragraph, after summarizing Qualitest, I think	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. "And it is currently based on historical purchases by an individual customer (thresholds)." Did I read that correctly? A. Yes, you did. Q. Okay. Stated that you do not routinely visit customers to determine who they are selling to and "Qualitest does not visit their pharmacies or practitioners who dispense their product." Do you see that? A. Yes. Q. Do you recall discussing that with the DEA? A. I do. Q. So you don't dispute the characterization of the meeting? A. No. Q. Okay. "Ms. Hernandez stated the only individuals who visit their customers are
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	educational and informative. SC Levin stated he would discuss Qualitest's responsibilities under the Controlled Substances Act, their suspicious order monitoring system, their procedures concerning due diligence, knowing their customers, who their customers sell to and graphs depicting the pharmacies and practitioners where oxycodone in various formulations and hydrocodone in various formulations were ultimately dispensed from. Do you see that, ma'am? A. Yes. Q. And as an encapsulation, is that a good high level summary of what happened during the meeting? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Okay. It states that in the next	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. "And it is currently based on historical purchases by an individual customer (thresholds)." Did I read that correctly? A. Yes, you did. Q. Okay. Stated that you do not routinely visit customers to determine who they are selling to and "Qualitest does not visit their pharmacies or practitioners who dispense their product." Do you see that? A. Yes. Q. Do you recall discussing that with the DEA? A. I do. Q. So you don't dispute the characterization of the meeting? A. No. Q. Okay. "Ms. Hernandez stated the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	educational and informative. SC Levin stated he would discuss Qualitest's responsibilities under the Controlled Substances Act, their suspicious order monitoring system, their procedures concerning due diligence, knowing their customers, who their customers sell to and graphs depicting the pharmacies and practitioners where oxycodone in various formulations and hydrocodone in various formulations were ultimately dispensed from. Do you see that, ma'am? A. Yes. Q. And as an encapsulation, is that a good high level summary of what happened during the meeting? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Okay. It states that in the next paragraph, after summarizing Qualitest, I think	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. "And it is currently based on historical purchases by an individual customer (thresholds)." Did I read that correctly? A. Yes, you did. Q. Okay. Stated that you do not routinely visit customers to determine who they are selling to and "Qualitest does not visit their pharmacies or practitioners who dispense their product." Do you see that? A. Yes. Q. Do you recall discussing that with the DEA? A. I do. Q. So you don't dispute the characterization of the meeting? A. No. Q. Okay. "Ms. Hernandez stated the only individuals who visit their customers are
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	educational and informative. SC Levin stated he would discuss Qualitest's responsibilities under the Controlled Substances Act, their suspicious order monitoring system, their procedures concerning due diligence, knowing their customers, who their customers sell to and graphs depicting the pharmacies and practitioners where oxycodone in various formulations and hydrocodone in various formulations were ultimately dispensed from. Do you see that, ma'am? A. Yes. Q. And as an encapsulation, is that a good high level summary of what happened during the meeting? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Okay. It states that in the next paragraph, after summarizing Qualitest, I think it's the third sentence or fourth sentence, it	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. "And it is currently based on historical purchases by an individual customer (thresholds)." Did I read that correctly? A. Yes, you did. Q. Okay. Stated that you do not routinely visit customers to determine who they are selling to and "Qualitest does not visit their pharmacies or practitioners who dispense their product." Do you see that? A. Yes. Q. Do you recall discussing that with the DEA? A. I do. Q. So you don't dispute the characterization of the meeting? A. No. Q. Okay. "Ms. Hernandez stated the only individuals who visit their customers are from the sales force and not compliance."

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                                                                                                          Page 256
                                                                1
 1
        seeking to update your computer system and to
                                                                      reflected in your takeaway bullet points, fair?
 2
                                                                2
        improve the suspicious order monitoring system.
                                                                           A.
                                                                                 Yes.
 3
                 Do you see that?
                                                                3
                                                                           Q.
                                                                                 Okay.
 4
                  Yes, I do.
                                                                Δ
                                                                                 He's basically going over the
             A.
                                                                           A.
 5
                  Okay. Apparently, you presented
                                                                5
                                                                      regulations in general and the things that
             Q.
                                                                6
 6
        some organizational structure of Endo and the
                                                                      they're seeing.
 7
        subsidiaries, and then you "stated that over 50
                                                                7
                                                                           Q. Okay. Also says, you know, you
                                                                8
 8
        percent of the firm's sales are controlled
                                                                      should be reviewing what the DEA has done, our
                                                                9
 9
                                                                      investigations, things that you read more
        substances."
10
                 Do you see that?
                                                              10
                                                                      publicly on websites concerning customers and
11
             A.
                  Yes.
                                                              11
                                                                      customers of customers, fair?
12
                                                              12
             O.
                  I want to focus on the next
                                                                           A.
                                                                                Yes.
                                                              13
13
                                                                                And then it talks about the
        paragraph.
14
                                                              14
                  "SC Levin stated that 80 percent
                                                                      PowerPoint that he presented and some bullets
15
        of all controlled substances manufactured in the
                                                              15
                                                                      that we don't need to revisit in great depth
                                                              16
                                                                      but, again, echoing this concept that closed
16
        world are prescribed and consumed in the United
17
        States."
                                                              17
                                                                      system of controlled substance distribution,
18
                                                              18
                 Do you recall this discussion?
                                                                      correct?
19
                                                              19
                                                                                MS. VANNI: Object to form.
             A.
                 Yes.
                                                              20
20
                                                                                THE WITNESS: Yes.
                  Okay. SC Levin stated that the
21
        abuse and diversion of oxycodone 15 and
                                                              21
                                                                      BY MR. BUCHANAN:
22
        30-milligram tablets is a major problem.
                                                              22
                                                                                And then it notes what the graphs
23
                 Do you recall that?
                                                              23
                                                                      depicted at the end of the first page, yes. The
24
                                                              24
             A.
                 Yes.
                                                                      graphs depicted or the graphs revealed several
                                            Page 255
                                                                                                          Page 257
                                                                1
 1
             Q. Do you recall that being a major
                                                                      pharmacies purchasing large quantities of
 2
        problem at this point in time?
                                                                2
                                                                      oxycodone and hydrocodone products from
 3
                 MS. VANNI: Object to form.
                                                                3
                                                                      Qualitest's customers. The graph showed the
                                                                4
 4
                 THE WITNESS: I recall him saying
                                                                      pharmacies in Florida purchased very large
 5
                                                                5
                                                                      quantities of Qualitest's oxycodone products.
             it was a major problem, yes.
                                                                6
 6
        BY MR. BUCHANAN:
                                                                      Also, the graphs show that pharmacies in Texas
 7
                                                                7
                  Okay. "SC Levin discussed the
                                                                      and California purchased large quantities of
 8
        pain clinic issues found in Florida, as well as
                                                                8
                                                                      Qualitest's hydrocodone products.
 9
                                                                9
        other drug abuse trends across the country. SC
                                                                      Ms. Hernandez, Ms. Hudson and Ms. Patel were
10
                                                              10
        Levin outlined the methods of diversion of these
                                                                      completely unaware of where Qualitest products
11
                                                              11
        products and advised that Qualitest is
                                                                      were ending up.
                                                              12
12
        responsible for monitoring and reviewing their
                                                                               As of that point in time, ma'am,
13
                                                              13
        suspicious order monitoring system, assuring
                                                                      were you completely unaware of where Qualitest's
14
        Qualitest is reporting to ARCOS correctly,
                                                              14
                                                                      products were ending up?
                                                              15
15
                                                                           A. No. What this refers to is that
        visiting and knowing their customers,
16
                                                              16
        maintaining a due diligence file on their
                                                                      we were unaware of the secondary customers. So
17
        customers, and knowing where their products are
                                                              17
                                                                      we ship to the customers and we were aware who
18
        ending up."
                                                              18
                                                                      we were shipping to and, you know, the
                                                              19
19
                 Let's pause for a moment. First,
                                                                      information for them, but we did not have
                                                              20
20
        did I read that correctly?
                                                                      visibility of the customers that they then
21
                                                              21
             A.
                  Yes.
                                                                      shipped to.
22
             Q.
                  And you recall that discussion?
                                                              22
                                                                           Q. Right, as of that point in time,
23
                                                              23
                                                                      ma'am, you were not looking at really the
             A.
24
                                                              24
                  Okay. And then some of that's
                                                                      customers of customers in terms of what they
```

```
Page 258
                                                                                                         Page 260
 1
                                                               1
                                                                     and as seen in their ARCOS data," is what, what
         were receiving, right?
 2
                                                               2
                   Correct. We didn't have data
                                                                     did he sav?
 3
        available to us.
                                                               3
                                                                               He said "inadequate to say the
                                                               4
                                                                     least."
 4
              Q. Well, there is chargeback data
                                                               5
                                                                          Q. Do you recall this discussion
 5
         that the company ultimately looked at, fair?
                                                               6
                                                                     with the DEA in March of 2013?
 6
                  MS. VANNI: Object to form.
 7
                  THE WITNESS: Yes, that gave
                                                               7
                                                                          A. I don't recall it being said to
                                                               8
 8
                                                                     us as being inadequate during the meeting.
              11S --
                                                               9
 9
                                                                               I do recall us telling them of
         BY MR. BUCHANAN:
10
                                                             10
                                                                     some of the things that we were looking at and
              Q. In fact, the DEA told you you
11
        need to be looking at that, right?
                                                             11
                                                                     wanted to implement and them stating that that
                  MS. VANNI: Object to form.
                                                             12
                                                                     was good, that they, you know, supported that
12
                                                             13
13
                  THE WITNESS: The DEA told us
                                                                     and that we should move forward with taking
                                                             14
14
              that we should look at it because that's
                                                                     those additional steps.
15
                                                             15
                                                                               And they gave you a window of
              what they were hearing from other
                                                             16
                                                                     time to do this, and they were going to come
16
              manufacturers, that they were looking
                                                             17
                                                                     back and talk to you to make sure you had done
17
              into that and trying to see if they
                                                             18
18
              could get data from it.
                                                                     it, right?
                                                             19
                                                                               MS. VANNI: Object to form.
19
        BY MR. BUCHANAN:
                                                             20
20
              Q. And, in fact, you contracted to
                                                                               THE WITNESS: I don't believe --
21
        after this meeting and started to implement a
                                                             21
                                                                          I don't believe there was a you must
22
         process where you reviewed and considered
                                                             22
                                                                          follow up with us type of mentality. I
23
         chargeback data, correct?
                                                             23
                                                                          think that was us saying we wanted to go
                                                             24
                                                                          back and talk to DEA and show them the
24
              A. Yes, we did try.
                                           Page 259
                                                                                                         Page 261
 1
            Q. Okay. You, in fact, did
                                                               1
                                                                          things we had implemented.
 2
                                                               2
        implement the consideration of chargeback data
                                                                     BY MR. BUCHANAN:
 3
        as part of your SOMS process, correct?
                                                               3
                                                                               It stated that "SC Levin stated
 4
            A. Not while I was at Qualitest. It
                                                               4
                                                                     that should Qualitest or any firm who had been
 5
        was something -- I don't know if anything was --
                                                               5
                                                                     briefed was found to have violated the CSA
 6
        happened afterwards, but while I was there, we
                                                               6
                                                                     pertaining to what was discussed during the
 7
        were not able to get any good data out of it.
                                                               7
                                                                     course of the meeting, DEA could seek
 8
            Q. Okay. Let's pause and see if I
                                                               8
                                                                     administrative or civil action to remedy the
 9
                                                               9
        can refresh your memory on that during our
                                                                     violation."
10
                                                             10
        examination today.
                                                                               Did I read that correctly?
11
                                                             11
            A. Sure.
                                                                          A. Yes.
12
            Q. It then continues that "SC Levin
                                                             12
                                                                               Okay. You were further guided, I
13
                                                             13
        stated that Qualitest must review the chargeback
                                                                     think it's the last sentence here. SC Levin
14
        information which they have access to,
                                                             14
                                                                     told Ms. Hernandez to educate Qualitest
15
        immediately address deficiencies in their
                                                             15
                                                                     employees who have access to controlled
16
                                                             16
        suspicious order monitoring system, have
                                                                     substances on what they discussed today -- or
17
        compliance people visit their customers to
                                                             17
                                                                     what was discussed today and communicate with
18
        review their suspicious order monitoring system
                                                             18
                                                                     her local DEA office, should she have any
19
        and review the top customers of their customers
                                                             19
                                                                     questions.
20
        and pay visits to pharmacies that purchase their
                                                             20
                                                                               Did I read that correctly?
21
        products. SC Levin advised Ms. Hernandez that
                                                             21
                                                                          A. Yes.
22
        Qualitest must know their customers and maintain
                                                             22
                                                                               Okay. Well, let's talk -- let's
23
                                                             23
                                                                     talk about the implementation steps. Oh,
        a due diligence file on them. SC Levin stated
24
                                                             24
        Qualitest's current system as explained to him
                                                                     actually, one more document to complete this.
```

	Page 262		Page 264
1	MR. BUCHANAN: 619, please.	1	A. So I reported to Sanjay, who
2	(Document marked for	2	reported to Jill who reported to Denise.
3	identification as Par-Norton Deposition	3	Q. Thank you.
4	Exhibit No. 11.)	4	A. Sorry.
5	BY MR. BUCHANAN:	5	Q. So Ms. Hudson was not able to
6	Q. I guess before we move off the	6	attend the meeting in person, she participated
7	last exhibit, that generally reflects the	7	by phone and took notes while you all were in
8	meeting and refreshes your recollection what	8	this discussion with the DEA, fair?
9	occurred that day?	9	A. Yes, with a very bad connection.
10	MS. VANNI: Object to form.	10	Q. Okay. All right. Well, let's go
11	THE WITNESS: Generally, yes.	11	midway on point two. What's reflected here in
12	I'm sure that every distributor had	12	the middle, "Tracey: we were looking at our SOM
13	almost word for word the same minutes.	13	program just before Lenny called us."
14	BY MR. BUCHANAN:	14	You see that in the middle of the
15	Q. In other words, this was a	15	page, just kind of a back-and-forth, SOM
16	meeting that was a meeting that was being had	16	
17	generally; is that what you're saying?	17	program? A. Mm-hmm, yes.
18	A. Correct. I mean, it was DEA	18	A. Mm-hmm, yes.Q. There's a question about whether
	· · · · · · · · · · · · · · · · · · ·		*
19	was doing the same meeting with all distributors	19 20	you're looking at chargeback data to help you
20	and basically providing the same message.		understand what your customers' customers are
21	Q. And so you had that same type of	21	doing. You respond, "we were looking at our SOM
22	meeting with that same type of message with Anda	22	program just before Lenny called us."
23	or Anda back in 2009 or whenever that meeting	23	Do you see that?
24	occurred?	24	A. Yes.
			Page 265
1	MS. KOSKI: Object to form.	1	_
	MR. SCHACK: Objection.		Q. Lenny was the local DEA agent?
2	THE WITNESS: Yes.	2 3	A. Lenny was at headquarters.
			Q. And Lenny is the one who called
4	MR. BUCHANAN: Thank you.	4	you to say we need you to come to DC?
5	Passing over what we're marking	5	A. Yes.
6	as Exhibit 11. Can we pull up 619 on	6	Q. Got you, okay.
7	the screen.	7	Then you were asked you asked
8	BY MR. BUCHANAN:	8	to see what your customer SOM program is
9	Q. Okay. This is an e-mail from	9	relative to your products, you responded "Right
	N II 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		a contract the second s
10	Ms. Hudson to several of the same people we've	10	now, our sales team is visiting our customers."
10 11	been talking about, including yourself, Ms.	11	Do you see that?
10 11 12	been talking about, including yourself, Ms. Connell and Sanjay Patel.	11 12	Do you see that? A. Yes.
10 11 12 13	been talking about, including yourself, Ms. Connell and Sanjay Patel. Do you see that?	11 12 13	Do you see that? A. Yes. Q. Okay. And then it says, you
10 11 12 13 14	been talking about, including yourself, Ms. Connell and Sanjay Patel. Do you see that? A. Yes.	11 12 13 14	Do you see that? A. Yes. Q. Okay. And then it says, you really need to know who your customers are
10 11 12 13 14 15	been talking about, including yourself, Ms. Connell and Sanjay Patel. Do you see that? A. Yes. Q. Denise Hudson worked in your	11 12 13 14 15	Do you see that? A. Yes. Q. Okay. And then it says, you really need to know who your customers are selling to."
10 11 12 13 14	been talking about, including yourself, Ms. Connell and Sanjay Patel. Do you see that? A. Yes. Q. Denise Hudson worked in your group?	11 12 13 14	Do you see that? A. Yes. Q. Okay. And then it says, you really need to know who your customers are selling to." Do you see that in the beginning
10 11 12 13 14 15 16	been talking about, including yourself, Ms. Connell and Sanjay Patel. Do you see that? A. Yes. Q. Denise Hudson worked in your group? A. Denise was there was Denise	11 12 13 14 15	Do you see that? A. Yes. Q. Okay. And then it says, you really need to know who your customers are selling to."
10 11 12 13 14 15	been talking about, including yourself, Ms. Connell and Sanjay Patel. Do you see that? A. Yes. Q. Denise Hudson worked in your group?	11 12 13 14 15 16	Do you see that? A. Yes. Q. Okay. And then it says, you really need to know who your customers are selling to." Do you see that in the beginning
10 11 12 13 14 15 16	been talking about, including yourself, Ms. Connell and Sanjay Patel. Do you see that? A. Yes. Q. Denise Hudson worked in your group? A. Denise was there was Denise and then Jill and then Sanjay and then myself. Q. Okay. And then the written	11 12 13 14 15 16 17	Do you see that? A. Yes. Q. Okay. And then it says, you really need to know who your customers are selling to." Do you see that in the beginning of the next page?
10 11 12 13 14 15 16 17	been talking about, including yourself, Ms. Connell and Sanjay Patel. Do you see that? A. Yes. Q. Denise Hudson worked in your group? A. Denise was there was Denise and then Jill and then Sanjay and then myself.	11 12 13 14 15 16 17 18	Do you see that? A. Yes. Q. Okay. And then it says, you really need to know who your customers are selling to." Do you see that in the beginning of the next page? A. I do.
10 11 12 13 14 15 16 17 18	been talking about, including yourself, Ms. Connell and Sanjay Patel. Do you see that? A. Yes. Q. Denise Hudson worked in your group? A. Denise was there was Denise and then Jill and then Sanjay and then myself. Q. Okay. And then the written	11 12 13 14 15 16 17 18 19	Do you see that? A. Yes. Q. Okay. And then it says, you really need to know who your customers are selling to." Do you see that in the beginning of the next page? A. I do. Q. Okay. And DEA told you, as
10 11 12 13 14 15 16 17 18 19 20	been talking about, including yourself, Ms. Connell and Sanjay Patel. Do you see that? A. Yes. Q. Denise Hudson worked in your group? A. Denise was there was Denise and then Jill and then Sanjay and then myself. Q. Okay. And then the written record won't reflect what you just did, so	11 12 13 14 15 16 17 18 19 20	Do you see that? A. Yes. Q. Okay. And then it says, you really need to know who your customers are selling to." Do you see that in the beginning of the next page? A. I do. Q. Okay. And DEA told you, as reflected in Ms. Hudson's notes, "We like to
10 11 12 13 14 15 16 17 18 19 20 21	been talking about, including yourself, Ms. Connell and Sanjay Patel. Do you see that? A. Yes. Q. Denise Hudson worked in your group? A. Denise was there was Denise and then Jill and then Sanjay and then myself. Q. Okay. And then the written record won't reflect what you just did, so maybe	11 12 13 14 15 16 17 18 19 20 21	Do you see that? A. Yes. Q. Okay. And then it says, you really need to know who your customers are selling to." Do you see that in the beginning of the next page? A. I do. Q. Okay. And DEA told you, as reflected in Ms. Hudson's notes, "We like to differentiate between salespeople and DEA

	Page 266		Page 268
1	Q. Do you recall that discussion, at	1	robust SOM program?
2	least when you were with the DEA?	2	MS. VANNI: Object to form.
3	A. I do.	3	THE WITNESS: Actually, I don't
4	Q. Okay. And then she characterized	4	feel I don't feel the quantity is a
5	the discussion this way in the middle of that	5	factor.
6	paragraph, "We want you to look at this, decide	6	BY MR. BUCHANAN:
7	what to do about it. If we show up at your	7	Q. Okay. A company should have a
8	facility in 6 to 9 months, we want to see some	8	robust SOM program and strong measures to
9	improvement. We need a good SOM program that is	9	prevent diversion regardless of the quantity,
10	adequate for the type of business we are in. We	10	correct?
11	are responsible for these products. DEA is not	11	MS. VANNI: Object to form.
12	interested in interfering with legitimate needs	12	THE WITNESS: Yes.
13	of patients."	13	BY MR. BUCHANAN:
14	Do you see that?	14	Q. But, certainly, if a company's
15	A. Yes.	15	entire business, to the tune of billions and
16	Q. Did I read that correctly?	16	billions of pills and many billions of dollars
17	A. Yes, you did.	17	in sales is with controlled substances, they
18	Q. Okay. And you recall that as	18	should invest the resources in a robust SOM
19	being a component of your discussion with the	19	program; you could agree with me, right?
20	DEA that day?	20	MS. VANNI: Object to form.
21	A. I think it's interspersed with	21	THE WITNESS: Yes.
22	some of her opinion as well, but generally, yes.	22	MR. BUCHANAN: So let's one
23	Q. Okay. But you do recall that, in	23	other document. Can I have 581.
24	general, that the DEA told you that when we come	24	THE VIDEOGRAPHER: Counsel, can
	Page 267		Page 269
1	back to you in six to nine months, we need	1	we go off the record momentarily. I do
2	improvement?	2	apologize, just going off the record
3	MC VANINI: Object to form		
	MS. VANNI: Object to form.	3	momentarily. The time is 1:25 p m.
4	THE WITNESS: I don't recall.	3 4	momentarily. The time is 1:25 p m. (Pause.)
4 5	THE WITNESS: I don't recall. BY MR. BUCHANAN:		momentarily. The time is 1:25 p m. (Pause.) THE VIDEOGRAPHER: Back on the
	THE WITNESS: I don't recall. BY MR. BUCHANAN: Q. Okay. It says, "We need a good	4	momentarily. The time is 1:25 p m. (Pause.)
5	THE WITNESS: I don't recall. BY MR. BUCHANAN:	4 5	momentarily. The time is 1:25 p m. (Pause.) THE VIDEOGRAPHER: Back on the
5 6	THE WITNESS: I don't recall. BY MR. BUCHANAN: Q. Okay. It says, "We need a good	4 5 6	momentarily. The time is 1:25 p m. (Pause.) THE VIDEOGRAPHER: Back on the record, the time is 1:28 p.m.
5 6 7 8 9	THE WITNESS: I don't recall. BY MR. BUCHANAN: Q. Okay. It says, "We need a good SOM program that is adequate for the type of business we are in." Do you see that sentence?	4 5 6 7 8 9	momentarily. The time is 1:25 p m. (Pause.) THE VIDEOGRAPHER: Back on the record, the time is 1:28 p.m. (Document marked for identification as Par-Norton Deposition Exhibit No. 12.)
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5 6 7 8 9 10 11 12	THE WITNESS: I don't recall. BY MR. BUCHANAN: Q. Okay. It says, "We need a good SOM program that is adequate for the type of business we are in." Do you see that sentence? A. I do. Q. Do you agree, ma'am, as a general matter, that a company needs a SOM program that is adequate for the type of business that it's in? A. Yes.	4 5 6 7 8 9 10 11 12 13	momentarily. The time is 1:25 p m. (Pause.) THE VIDEOGRAPHER: Back on the record, the time is 1:28 p.m. (Document marked for identification as Par-Norton Deposition Exhibit No. 12.) MR. BUCHANAN: Ma'am, passing you what we marked as Exhibit 12. Do we have a copy for counsel yet? It's for the record, it's E606 and it's PAR_OPIOID_MDL 18920. MS. VANNI: Thank you.
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                                                                                                      Page 272
                                                             1
 1
                                                                            THE WITNESS: Yes.
                  Yes.
                                                             2
 2
                                                                   BY MR. BUCHANAN:
             Q.
                  So you were the head of DEA
 3
        compliance. You hired Mr. Brantley into your
                                                             3
                                                                        Q. Gigged is a confusing term.
                                                             4
                                                                            Getting, what, registrations
 4
        group, correct?
                                                             5
                                                                   pulled, fined, civil actions, suspension orders,
 5
                  Yes, I hired Larry first,
             A.
                                                             6
                                                                   all that kind of stuff?
 6
        Mr. Shaffer and then later hired Eric.
 7
                  When did you bring in Mr. -- is
                                                             7
                                                                        A. Yes, we were tracking it.
                                                             8
 8
        it Shaffer or Shaffer?
                                                                        Q. Okay. And so one of the things a
 9
                                                             9
                                                                   reasonable company does, and I guess this was a
                  Shaffer.
             A.
10
                                                            10
                                                                   responsible thing to do?
             Q. It's the two Fs that are throwing
11
        me there.
                                                            11
                                                                            MS. VANNI: Object to form.
12
                                                            12
                                                                            THE WITNESS: I think so. I
             A. I'm not sure exactly when.
                                                           13
13
             Q. I assume his e-mail address is
                                                                        think it helped to -- it helped to teach
14
        spelled right. All right. So when did you hire
                                                            14
                                                                        others in the company what ramifications
15
        him, by the way?
                                                            15
                                                                        there were if something were to go
                                                            16
16
             A. I'm not sure on exact -- the
                                                                        wrong.
17
                                                            17
        exact date, but he was, I believe, my first
                                                                   BY MR. BUCHANAN:
18
                                                            18
        hire.
                                                                        Q. And that's something that you
19
                  After the meeting with the DEA?
                                                            19
                                                                   have in a compliance department as a bit of an
             Q.
20
                  No. After getting to Qualitest.
                                                            20
                                                                   issue from time to time, right?
21
                  Okay. And he was, if I
                                                            21
                                                                            MS. VANNI: Object to form.
22
        understand right, he was more in this quota
                                                            22
                                                                            THE WITNESS: No company is
23
        management function, right?
                                                            23
                                                                        perfect.
                                                            24
                                                                   BY MR. BUCHANAN:
24
             A. He was at the company, however,
                                          Page 271
                                                                                                      Page 273
 1
       he actually had a -- he had handled suspicious
                                                             1
                                                                             Certainly not, certainly not, and
 2
       order monitoring previously.
                                                             2
                                                                   nor are people.
 3
                 Got you.
                                                             3
                                                                             But one of the issues you have in
 4
                 All right. So let's look at
                                                             4
                                                                   a compliance department is sometimes some
 5
       this. This is an e-mail from Mr. Shaffer to
                                                             5
                                                                   tension between compliance with what a
 6
       Mr. Brantley early October 2013, subject SOMS
                                                             6
                                                                   responsible company would do or reasonable
 7
                                                             7
       info, right?
                                                                   company would do or the regulations require and
 8
                                                             8
                                                                   what the business people want, right?
            A. Yes.
                                                             9
 9
                 SOMS violations as a spreadsheet,
                                                                            MS. VANNI: Objection.
            O.
10
                                                            10
       SOMS doc from 2013 and a SOMS presentation,
                                                                            THE WITNESS: I wouldn't
11
       right?
                                                            11
                                                                        necessarily say that there's tension
12
            A.
                                                            12
                                                                        from the aspect of, you know, everybody
                 Yes.
13
                                                            13
                 Okay. Do you remember during
                                                                        knows that you have to comply with the
            Q.
14
       your time at the company one of the things you
                                                            14
                                                                        DEA regulations. It's a matter of
15
       were tracking was who was getting in trouble?
                                                            15
                                                                        education, it really is.
16
                MS. VANNI: Object to form.
                                                            16
                                                                   BY MR. BUCHANAN:
17
                 THE WITNESS: Yes.
                                                            17
                                                                        Q. And so one of the things you did
18
       BY MR. BUCHANAN:
                                                            18
                                                                   was compile a list of all the bad things that
                                                            19
19
                 And you had an Excel spreadsheet
                                                                   could happen to us as a business with 70%
20
       that you put together and kind of tracked what
                                                            20
                                                                   controlled substances if we don't comply, right?
21
       was happening with different registrants who was
                                                            21
                                                                            MS. VANNI: Object to form.
22
       getting gigged and written up with big fines and
                                                            22
                                                                            THE WITNESS: Yes.
23
                                                            23
       stuff like that, right?
                                                                   BY MR. BUCHANAN:
24
                                                            24
                 MS. VANNI: Object to form.
                                                                        Q. Because this, you know, this is a
```

```
Page 274
                                                                                                    Page 276
        -- this could be a devastating consequence if we
                                                            1
                                                                  saying I needed to make sure I could get some
 1
        don't comply, right?
                                                            2
                                                                  budget to make this happen, so I had to show the
 2
 3
                 MS. VANNI: Object to form.
                                                            3
                                                                  other side of not doing it?
                 THE WITNESS: Yes.
                                                            4
                                                                           MS. VANNI: Object to form.
 4
 5
        BY MR. BUCHANAN:
                                                            5
                                                                           THE WITNESS: I was expecting
 6
                                                            6
            O. Fair, yeah.
                                                                       more resistance, ves.
 7
                 So one of the things that's
                                                            7
                                                                  BY MR. BUCHANAN:
                                                            8
 8
        helpful in certainly getting management's
                                                                       Q. Okay. And so you put together
        attention is you should know distribution
 9
                                                            9
                                                                  this schedule, and let's look at the -- let's be
        facilities have been closed, right?
10
                                                          10
                                                                  clear, I guess, because I may not have time to
11
            A. Mm-hmm.
                                                          11
                                                                  come back to this today.
12
                That's a yes answer?
                                                          12
                                                                           Some of what we see here in the
            O.
                Yes. Sorry.
                                                          13
13
            A.
                                                                  SOMS violations are, for example, we see a
                You should know that tens of
                                                          14
                                                                  reference to Walgreens.
14
15
        millions of dollars in fines have been imposed
                                                          15
                                                                           MR. BUCHANAN: Could we go to
        against certain distributors, right?
                                                          16
                                                                       606.4. Can you blow up this one right
16
                MS. VANNI: Object to form.
17
                                                          17
                                                                       here, if you can see my finger. Thank
18
                 THE WITNESS: Yes.
                                                          18
                                                                       you, yeah. My eyes are failing me,
19
        BY MR. BUCHANAN:
                                                          19
                                                                       guys. Sorry about that.
20
                                                          20
                                                                           MR. SCHACK: Counsel, do you have
            Q. You should know that we have a
                                                                       any other copies of this exhibit that
21
        distributor license, right?
                                                          21
22
            A. Yes.
                                                          22
                                                                       you can share?
23
            Q. And if we're not doing our job,
                                                          23
                                                                           MR. BUCHANAN: There's an extra
        this could be devastating, right?
                                                          24
                                                                       floater if somebody can pass the floater
24
                                         Page 275
                                                                                                    Page 277
                 MS. VANNI: Object to form.
 1
                                                            1
                                                                       down.
                 THE WITNESS: Well, it could
 2
                                                            2
                                                                           MR. SCHACK: Thank you.
 3
            impact the business, yes.
                                                            3
                                                                  BY MR. BUCHANAN:
        BY MR. BUCHANAN:
                                                                       Q. Okay. All right. So this is
 4
                                                            4
 5
                 Certainly.
                                                            5
                                                                  suspension order that you tracked, a suspension
                                                                  of a DEA license relating to a Walgreens
 6
                 And so you bring these items to
                                                            6
 7
        the attention of people above you to say, look,
                                                            7
                                                                  distribution center in Jupiter, Florida.
                                                                           Do you remember that?
 8
        this could affect our pocketbook, right?
                                                            8
                 MS. VANNI: Objection.
                                                            9
 9
                                                                           Yes.
                                                                       A.
                THE WITNESS: Actually, no. The
10
                                                          10
                                                                       Q. Do you remember -- you were aware
            reason that we use these was because I
                                                                  of that when it happened in 2012, right, as
11
                                                          11
                                                                  somebody who reads the Federal Register, as
12
            knew that the electronic system that I
                                                          12
                                                                  somebody who attends DEA conferences?
            wanted to implement was very expensive,
                                                          13
13
14
            and I needed to have adequate
                                                          14
                                                                       A. Yes.
            justification to support that system
                                                          15
                                                                       O. Okay. And then off to the right
15
            because -- because we did have something
                                                          16
                                                                  we see really what you guys were doing, right,
16
17
            in place, so I knew that the feedback I
                                                          17
                                                                  and this is your drug that was being shipped in
18
            would get is that we were complying with
                                                          18
                                                                  to Florida, right?
            the regulation. So I wanted to show
19
                                                          19
                                                                           MS. VANNI: Object to the form.
            them some of the things that the other
                                                                           THE WITNESS: I can't read it.
20
                                                          20
21
            companies were doing that DEA
                                                          21
                                                                  BY MR. BUCHANAN:
22
            categorized as not enough.
                                                          22
                                                                       Q. Yeah, it's a challenge with, I
        BY MR. BUCHANAN:
                                                                  don't know, spreadsheets. There's a
23
                                                          23
            Q. Right. I mean, basically, you're
                                                                  heading that's --
24
                                                          24
```

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1	MR. BUCHANAN: Bradley, I'm	1	particular distribution facility that had its
2	sorry, I think it's confusing for people	2	license suspended in 2012, correct?
3	if you do it the way you've done it,	3	A. Yes, looks that way.
4	because at the top it says "Violation."	4	Q. Of 2009 there were 11 million
5	BY MR. BUCHANAN:	5	dosage units, right, Walgreens Jupiter, and you
6	Q. Let's just read across the top	6	know I think I misspoke. Let me restate this,
7	together, ma'am. You see Violation For	7	okay.
8	there's Date, Violation For: Company, Violation,	8	What's at the top, I believe, are
9	Penalty, a web link, What they did, and What we	9	the dosage units shipped into Florida.
10	are doing.	10	Do you see that?
11	Do you see that?	11	A. Yes.
12	A. Yes.	12	Q. 83 million dosage units shipped
13	Q. Okay. So then there's that	13	into Florida, right? Am I reading it correctly?
14	reference for the Walgreens facility that we	14	A. I can't see.
15	were just looking at, and you see there's a	15	Q. I wish I could do more to help
16	narrative description of what happened with that	16	you on that.
17	one?	17	A. Yes, it states that 83,000
18	A. Yes.	18	83 million doses were sent to Florida in the
19	MR. BUCHANAN: And then I need	19	same time frame.
20	you to blow up, if you could, Bradley,	20	Q. And then in 2009 you shipped
21	the units all the way to the right.	21	11.6 million dosage units to the Jupiter
22	Keep going. Can you make the box a	22	facility of Walgreens, right?
23	little bigger so we don't clip off the	23	A. Yes.
24	top. Thanks.	24	Q. In 2010 you shipped 7 million to
	Page 279		Page 281
1	BY MR. BUCHANAN:	1	that one?
2	Q. Okay. All right. It doesn't get	2	A. Yes.
3	any bigger, but at least it's a little more in	3	Q. And then apparently in 2011 they
4	focus for you.	4	went to another facility, right?
5	So what we see here is Walgreens	5	A. Yes.
6	has a situation with their distribution center	6	Q. Okay. So over those two years
7	severe enough that their license is suspended	7	that we have data for, it doesn't go back prior
8	for that particular distribution facility.	8	to 2009, there's some, you know, 18 million,
9	Do you recall that?	9	19 million, 18 and a half million, I guess to be
10	A. Yes.	10	precise, dosage units of controlled substances
11	Q. Okay. And then what you did is	11	going to the facility that the DEA suspended its
12	you looked at, hey, what are we doing with them,	12	license in 2012, correct?
13	right?	13	A. Yes.
14	MS. VANNI: Object to form.	14	MS. VANNI: Object to form.
15	BY MR. BUCHANAN:	15	BY MR. BUCHANAN:
16	Q. Do you see that?	16	Q. Okay. And the allegation of the
17	A. Mm-hmm.	17	DEA was that that facility and the reason for
18	Q. And it shows here that over the	18	the suspension of a license was that they failed
19	same period of time, or I guess really from	19	to maintain effective controls against diversion
20	2009, 2010, 2011, your company, Qualitest	20	of controlled substances, right?
	shipped how many pills, 83 million pills, right?	21	A. Yes.
21	T.T		O And so major to major to 2012
22	You see that?	22	Q. And so prior to prior to 2013,
	You see that? A. Yes. Q. Shipped 83 million pills to that	23 24	ma'am, I take it are you aware of any site visits to Walgreens Jupiter?

	Page 282		Page 284
1	A. Again, I don't know what the	1	Do you see that there is
2	sales team did, so I don't know if they went to	2	information for other entities had their
3	went there or not.	3	registrations pulled or suspended or there were
4	Q. We know the DEA's conclusion, at	4	allegations against with regard to effective
5	least as reflected here, was that they failed to	5	controls against diversion on this sheet?
6	be they were not maintaining effective	6	MS. VANNI: Object to the
7	controls against diversion, right?	7	colloquy.
8	A. Yes.	8	THE WITNESS: Yes, that's what
9	Q. Okay. And had you asked for	9	I mean, there are that's what this is
10	copies of their suspicious order monitoring	10	a list of violations, yes.
11	protocols prior to 2013?	11	BY MR. BUCHANAN:
12	A. Again, I don't know.	12	Q. There's too many for us to read
13	Q. Okay. I mean, there's a list of	13	and it's almost too challenging to put on the
14	violations that are noted over several years in	14	screen but
15	this spreadsheet, correct?	15	A. Yes.
16	A. Yes.	16	Q just for the jury's benefit,
17	Q. For various entities, some are	17	there are other manufacturers, other
18	retail pharmacies, some are distributors,	18	distributors, other pharmacies referenced,
19	correct?	19	correct?
20	A. Yes, mm-hmm.	20	MS. VANNI: Object to form.
21	Q. And these are all obviously	21	THE WITNESS: Yes.
22	events that have happened prior to the time of	22	BY MR. BUCHANAN:
23	this PowerPoint, right?	23	Q. Okay. And there are other areas
24	A. Yes, they are.	24	where it is listed that you are, in fact,
	, ,		, , ,
	Page 283		D 20E
	1490 200		Page 285
1	Q. And we could agree, couldn't we,	1	shipping into that particular customer or
1 2		1 2	
	Q. And we could agree, couldn't we,		shipping into that particular customer or
2	Q. And we could agree, couldn't we, ma'am, that you're not aware of any request to	2	shipping into that particular customer or community. Do you see the column "What are we
2	Q. And we could agree, couldn't we, ma'am, that you're not aware of any request to any of the entities on this sheet for request	2	shipping into that particular customer or community. Do you see the column "What are we doing" on page 606.5 and 606.4?
2 3 4	Q. And we could agree, couldn't we, ma'am, that you're not aware of any request to any of the entities on this sheet for request for their suspicious order monitoring program or	2 3 4	shipping into that particular customer or community. Do you see the column "What are we doing" on page 606.5 and 606.4? A. I do, yes.
2 3 4 5	Q. And we could agree, couldn't we, ma'am, that you're not aware of any request to any of the entities on this sheet for request for their suspicious order monitoring program or practices prior to the times of these	2 3 4 5	shipping into that particular customer or community. Do you see the column "What are we doing" on page 606.5 and 606.4? A. I do, yes. Q. And there are other customers
2 3 4 5 6	Q. And we could agree, couldn't we, ma'am, that you're not aware of any request to any of the entities on this sheet for request for their suspicious order monitoring program or practices prior to the times of these violations, correct?	2 3 4 5 6	shipping into that particular customer or community. Do you see the column "What are we doing" on page 606.5 and 606.4? A. I do, yes. Q. And there are other customers that you were, in fact, fulfilling orders for
2 3 4 5 6 7	Q. And we could agree, couldn't we, ma'am, that you're not aware of any request to any of the entities on this sheet for request for their suspicious order monitoring program or practices prior to the times of these violations, correct? MS. VANNI: Objection. THE WITNESS: I'm not sure. I don't know.	2 3 4 5 6 7	shipping into that particular customer or community. Do you see the column "What are we doing" on page 606.5 and 606.4? A. I do, yes. Q. And there are other customers that you were, in fact, fulfilling orders for that had their licenses suspended or other
2 3 4 5 6 7 8	Q. And we could agree, couldn't we, ma'am, that you're not aware of any request to any of the entities on this sheet for request for their suspicious order monitoring program or practices prior to the times of these violations, correct? MS. VANNI: Objection. THE WITNESS: I'm not sure. I don't know. BY MR. BUCHANAN:	2 3 4 5 6 7 8	shipping into that particular customer or community. Do you see the column "What are we doing" on page 606.5 and 606.4? A. I do, yes. Q. And there are other customers that you were, in fact, fulfilling orders for that had their licenses suspended or other consequences? A. Yes. MS. VANNI: Object to form.
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2 3 4 5 6 7 8 9	Q. And we could agree, couldn't we, ma'am, that you're not aware of any request to any of the entities on this sheet for request for their suspicious order monitoring program or practices prior to the times of these violations, correct? MS. VANNI: Objection. THE WITNESS: I'm not sure. I don't know. BY MR. BUCHANAN: Q. You don't have any information, sitting here today, that you did so?	2 3 4 5 6 7 8 9 10 11 12	shipping into that particular customer or community. Do you see the column "What are we doing" on page 606.5 and 606.4? A. I do, yes. Q. And there are other customers that you were, in fact, fulfilling orders for that had their licenses suspended or other consequences? A. Yes. MS. VANNI: Object to form. THE WITNESS: Keep in mind as well that when when there is a a
2 3 4 5 6 7 8 9 10 11	Q. And we could agree, couldn't we, ma'am, that you're not aware of any request to any of the entities on this sheet for request for their suspicious order monitoring program or practices prior to the times of these violations, correct? MS. VANNI: Objection. THE WITNESS: I'm not sure. I don't know. BY MR. BUCHANAN: Q. You don't have any information, sitting here today, that you did so? MS. VANNI: Objection.	2 3 4 5 6 7 8 9 10 11 12 13	shipping into that particular customer or community. Do you see the column "What are we doing" on page 606.5 and 606.4? A. I do, yes. Q. And there are other customers that you were, in fact, fulfilling orders for that had their licenses suspended or other consequences? A. Yes. MS. VANNI: Object to form. THE WITNESS: Keep in mind as well that when — when there is a — a letter of admonition or issued by DEA
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. And we could agree, couldn't we, ma'am, that you're not aware of any request to any of the entities on this sheet for request for their suspicious order monitoring program or practices prior to the times of these violations, correct? MS. VANNI: Objection. THE WITNESS: I'm not sure. I don't know. BY MR. BUCHANAN: Q. You don't have any information, sitting here today, that you did so? MS. VANNI: Objection. THE WITNESS: Right, or did not. BY MR. BUCHANAN: Q. You have no information either	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	shipping into that particular customer or community. Do you see the column "What are we doing" on page 606.5 and 606.4? A. I do, yes. Q. And there are other customers that you were, in fact, fulfilling orders for that had their licenses suspended or other consequences? A. Yes. MS. VANNI: Object to form. THE WITNESS: Keep in mind as well that when when there is a a letter of admonition or issued by DEA for not conducting due diligence, for example, that doesn't mean they're not conducting due diligence on every
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. And we could agree, couldn't we, ma'am, that you're not aware of any request to any of the entities on this sheet for request for their suspicious order monitoring program or practices prior to the times of these violations, correct? MS. VANNI: Objection. THE WITNESS: I'm not sure. I don't know. BY MR. BUCHANAN: Q. You don't have any information, sitting here today, that you did so? MS. VANNI: Objection. THE WITNESS: Right, or did not. BY MR. BUCHANAN: Q. You have no information either way? A. Correct. Q. Fair enough. Okay. So let's go back to this document. And so tab one was I'm sorry, at	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	shipping into that particular customer or community. Do you see the column "What are we doing" on page 606.5 and 606.4? A. I do, yes. Q. And there are other customers that you were, in fact, fulfilling orders for that had their licenses suspended or other consequences? A. Yes. MS. VANNI: Object to form. THE WITNESS: Keep in mind as well that when when there is a a letter of admonition or issued by DEA for not conducting due diligence, for example, that doesn't mean they're not conducting due diligence on every customer that they have. That means the DEA found an example of that. If the license is getting suspended, they've probably found quite a few of them. However, that license was also
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And we could agree, couldn't we, ma'am, that you're not aware of any request to any of the entities on this sheet for request for their suspicious order monitoring program or practices prior to the times of these violations, correct? MS. VANNI: Objection. THE WITNESS: I'm not sure. I don't know. BY MR. BUCHANAN: Q. You don't have any information, sitting here today, that you did so? MS. VANNI: Objection. THE WITNESS: Right, or did not. BY MR. BUCHANAN: Q. You have no information either way? A. Correct. Q. Fair enough. Okay. So let's go back to this document. And so tab one was I'm sorry, at 606.4 we were just looking at violations, what	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	shipping into that particular customer or community. Do you see the column "What are we doing" on page 606.5 and 606.4? A. I do, yes. Q. And there are other customers that you were, in fact, fulfilling orders for that had their licenses suspended or other consequences? A. Yes. MS. VANNI: Object to form. THE WITNESS: Keep in mind as well that when — when there is a — a letter of admonition or issued by DEA for not conducting due diligence, for example, that doesn't mean they're not conducting due diligence on every customer that they have. That means the DEA found an example of that. If the license is getting suspended, they've probably found quite a few of them. However, that license was also reinstated, I believe, at a later date
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. And we could agree, couldn't we, ma'am, that you're not aware of any request to any of the entities on this sheet for request for their suspicious order monitoring program or practices prior to the times of these violations, correct? MS. VANNI: Objection. THE WITNESS: I'm not sure. I don't know. BY MR. BUCHANAN: Q. You don't have any information, sitting here today, that you did so? MS. VANNI: Objection. THE WITNESS: Right, or did not. BY MR. BUCHANAN: Q. You have no information either way? A. Correct. Q. Fair enough. Okay. So let's go back to this document. And so tab one was I'm sorry, at 606.4 we were just looking at violations, what the allegations were, the consequences were and	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	shipping into that particular customer or community. Do you see the column "What are we doing" on page 606.5 and 606.4? A. I do, yes. Q. And there are other customers that you were, in fact, fulfilling orders for that had their licenses suspended or other consequences? A. Yes. MS. VANNI: Object to form. THE WITNESS: Keep in mind as well that when when there is a a letter of admonition or issued by DEA for not conducting due diligence, for example, that doesn't mean they're not conducting due diligence on every customer that they have. That means the DEA found an example of that. If the license is getting suspended, they've probably found quite a few of them. However, that license was also reinstated, I believe, at a later date by DEA. So at some point DEA felt that
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And we could agree, couldn't we, ma'am, that you're not aware of any request to any of the entities on this sheet for request for their suspicious order monitoring program or practices prior to the times of these violations, correct? MS. VANNI: Objection. THE WITNESS: I'm not sure. I don't know. BY MR. BUCHANAN: Q. You don't have any information, sitting here today, that you did so? MS. VANNI: Objection. THE WITNESS: Right, or did not. BY MR. BUCHANAN: Q. You have no information either way? A. Correct. Q. Fair enough. Okay. So let's go back to this document. And so tab one was I'm sorry, at 606.4 we were just looking at violations, what	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	shipping into that particular customer or community. Do you see the column "What are we doing" on page 606.5 and 606.4? A. I do, yes. Q. And there are other customers that you were, in fact, fulfilling orders for that had their licenses suspended or other consequences? A. Yes. MS. VANNI: Object to form. THE WITNESS: Keep in mind as well that when — when there is a — a letter of admonition or issued by DEA for not conducting due diligence, for example, that doesn't mean they're not conducting due diligence on every customer that they have. That means the DEA found an example of that. If the license is getting suspended, they've probably found quite a few of them. However, that license was also reinstated, I believe, at a later date

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Page 286
                                                                                                        Page 288
                                                              1
 1
             back their license, basically.
                                                                         Q. Okay. At 606.14 there's a
        BY MR. BUCHANAN:
                                                              2
                                                                     summary of the current SOMS process.
 2
 3
                   Right. I mean, but the concern,
                                                              3
                                                                              Do you see that?
        obviously, and you've talked about it in your
                                                               4
                                                                         A. Yes, I do.
 4
        own writings, we've seen it from the DEA
                                                               5
                                                                         Q. Okay. And this would be the SOMS
 5
        presentation, we have it in your oral testimony
                                                               6
                                                                     process for Qualitest as of -- prior to the
 6
 7
        today is a closed system, right?
                                                              7
                                                                     revamping, right?
 8
             A. Yes.
                                                              8
                                                                         A. Prior to the upgrades, yes.
                                                              9
 9
                                                                              MS. VANNI: Object to form.
                 MS. VANNI: Object to form.
10
        BY MR. BUCHANAN:
                                                             10
                                                                     BY MR. BUCHANAN:
11
             Q. So if we don't have a closed
                                                             11
                                                                         Q. Okay. So the current SOMS
                                                             12
        system at a particular point in time, and I
                                                                     process is that -- was really directed at the
12
        think we looked at that spreadsheet where, I
13
                                                             13
                                                                     retail pharmacies, right?
        mean, there were billions of pills being made
                                                             14
                                                                             MS. VANNI: Object to form.
14
15
        every year of controlled substances by
                                                             15
                                                                             THE WITNESS: Yes.
        Qualitest, you'd agree?
                                                             16
16
                                                                     BY MR. BUCHANAN:
17
                 MS. VANNI: Object to form.
                                                             17
                                                                         Q. Okay. So prior to revamping,
18
                 THE WITNESS: Again, I can't
                                                             18
                                                                     SOMS procedures and monitoring of the orders was
19
             speak to those -- those numbers.
                                                             19
                                                                     not tied into the wholesale and distributor
20
        BY MR. BUCHANAN:
                                                             20
                                                                     customers, correct?
21
             Q. I'll represent to you that the
                                                             21
                                                                             MS. VANNI: Object to form.
        data that's been produced to us reflects that
22
                                                             22
                                                                              THE WITNESS: No, I would
23
        there were billions of pills of controlled
                                                             23
                                                                         disagree with that from the aspect of
        substances for hydrocodone and oxycodone that
24
                                                             24
                                                                         there was visibility -- in some cases
                                           Page 287
                                                                                                        Page 289
 1
        were being shipped every year, okay, accepting
                                                              1
                                                                         visibility to the inventories at the
 2
        that representation, if a manufacturer -- if
                                                              2
                                                                         wholesale level, so I think that
 3
        anyone in this chain has their head in the sand
                                                               3
                                                                         there -- they were being monitored, just
 4
        or isn't doing their job, then we don't have a
                                                               4
                                                                         not part of this process.
 5
                                                              5
        closed system?
                                                                     BY MR. BUCHANAN:
 6
                 MS. VANNI: Object to form.
                                                               6
                                                                         Q. Okay. Well, without trying to
 7
                                                              7
                 THE WITNESS: Yes, however, a
                                                                     kind of look backwards and figure out how maybe
 8
                                                              8
                                                                     that could have been done, what was reflected on
            violation from DEA --
                                                              9
 9
        BY MR. BUCHANAN:
                                                                     this particular document, 606.14, as Qualitest's
                                                             10
10
                 That's my question.
                                                                     current SOMS practices are these four bullet
11
                                                             11
                  -- a letter of admonition does
                                                                     points, correct?
12
        not mean that somebody had their head in the
                                                             12
                                                                         A. Yes.
                                                             13
13
        sand. Again, people make mistakes. Mistakes do
                                                                         Q. Does the -- does this document
14
        occur.
                                                             14
                                                                     describe anything being done with wholesalers?
                                                             15
                                                                              MS. VANNI: Object to form.
15
            Q. Okay, okay. And so when mistakes
16
        occur, okay, when there's negligence and --
                                                             16
                                                                              THE WITNESS: This document does
17
        withdrawn.
                                                             17
                                                                         not.
18
                 Let's go back to 606.14.
                                                             18
                                                                     BY MR. BUCHANAN:
                                                                         Q. Okay. Retail pharmacies, so one
19
                 This document, again, just to
                                                             19
                                                                     of the items is retail pharmacies under the
20
        reorient the jury, because we've been hoping
                                                             20
21
        around, at 606.1, this is the e-mail from
                                                             21
                                                                     current SOMS process are based on a product
22
        Mr. Shaffer to Mr. Brantley, people obviously in
                                                             22
                                                                     threshold amount, correct?
                                                             23
23
        your DEA compliance group, fair?
                                                                         A. Correct.
24
                                                             24
                                                                         Q. "Retail pharmacy threshold
            A.
                Yes.
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	Page 290		Page 292
1	amounts can be changed by the sales department,"	1	Q. Okay. And so as of this point in
2	right?	2	time, as of September 2013, this is some five
3	A. Yes.	3	months after your meeting with the DEA, these
4	O. And the threshold amounts are set	4	other classes of trades were not evaluated for
5		5	SOMS, correct?
6	by the sales department, right? A. Yes.	6	
7			A. Correct, not through the SOMS
	Q. And then the system holds the	7	program. Through the threshold program.
8	order until reviewed, right?	8	Q. We can agree that the people in
9	A. Yes.	9	the DEA compliance group who are at this point
10	Q. Okay. And so this is the SOMS	10	in time trying to respond to criticisms and
11	process as memorialized by Qualitest as of this	11	concerns concerning the SOMS program are
12	point in time, correct?	12	identifying issues with the process, right?
13	A. Correct.	13	MS. VANNI: Object to form.
14	Q. Okay. The next page sets forth	14	THE WITNESS: We're saying what's
15	the issues with that process, right?	15	wrong with the current process in order
16	A. The improvements that we'd like	16	to get improvements made.
17	to make.	17	BY MR. BUCHANAN:
18	Q. Well, what's written here is and	18	Q. Okay. Well, I mean, it wasn't
19	before somebody was asked to testify about it	19	false when they wrote it, was it? They wouldn't
20	A. Wording.	20	be lying to their boss about it, right?
21	Q. Yes, issues with the current	21	MS. VANNI: Object to form.
22	process, right?	22	THE WITNESS: No.
23	MS. VANNI: Object to the	23	BY MR. BUCHANAN:
24	colloquy.	24	Q. Okay. So we can agree that these
	Page 291		Page 293
1	Page 291	1	Page 293 were in fact issues with the then current
1 2	THE WITNESS: Yes.	1 2	were, in fact, issues with the then current
2	THE WITNESS: Yes. BY MR. BUCHANAN:	2	were, in fact, issues with the then current process prior to the revamping of the system in
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15 to see. 15 MS. VANNI: Object to form.	
16 BY MR. BUCHANAN: 16 THE WITNESS: It's somethin	_
Q. Well, and the DEA viewed this as 17 I did know based on the calls that	
18 a conflict of interest and considered the sales 18 made to me and the questions that	were
department as the department that is driven by 19 asked.	
20 what? 20 BY MR. BUCHANAN:	
21 A. Driven by dollars. 21 Q. Okay. We know that you did	
Q. Driven by sales? 22 visit or your sales team didn't visit ever	7
23 A. Mm-hmm. 23 customer, right?	
24 Q. Right? 24 A. Don't know that. I wasn't the	re
	10.

	Page 298		Page 300
1	Q. We know after some visits started	1	Do you see that, ma'am?
2	to occur that you did find some of those	2	A. Yes.
3	pharmacies like the pictures we looked at,	3	Q. And that was an issue with the
4	right?	4	current process as of October 2013?
5	MS. VANNI: Object to form.	5	A. The system didn't stop an order
6	THE WITNESS: Don't know about	6	because of an out of frequency or out of
7	that, but	7	pattern. However, part of looking at a
8	BY MR. BUCHANAN:	8	threshold quantity is to look at the history of
9	Q. The pharmacies that were doing	9	the account, which would give you the order
10	well more than 13% of their business in	10	frequency and pattern. So it wasn't picked up
11	controlled substances, right?	11	by the system automatically, but it was
12	A. 13% is an average, a guideline.	12	reviewed.
13	Q. Pharmacies that you had to cut	13	Q. Well, as of this point in time,
14	off?	14	we know you weren't reviewing other classes of
15	MS. VANNI: Object to form.	15	trade, right?
16	THE WITNESS: Pharmacies there	16	A. We were not as part of SOMS.
17	were customers that we reported to DEA,	17	Q. We know, at least what's written
18	I'm sure.	18	here, ma'am, is that there was "no check for
19		19	
20	BY MR. BUCHANAN:	20	order frequency and pattern discrepancies,"
	Q. There were customers after you		correct?
21	implemented a revised SOMS program that you had	21	A. Not by the initial electronic
22	to cut off, right?	22	system.
23	A. I believe so.	23	Q. Not by the system that could be
24	Q. Are you aware of any customer	24	reviewing the thousands and thousands of orders
			Page 301
1	that you cut off in the two years prior to	1	or line items that a company is getting, right?
2	implementing the new SOMS program?		MS. VANNI: Object to form.
	inibicinching the new SOMS brogram:	1 2	IVIS VAININI ODICCITOTOTII
3		2 3	
3 4	A. None that I can name, but I know	3	THE WITNESS: No, the system
4	A. None that I can name, but I know that there were some then as well.	3 4	THE WITNESS: No, the system would have been reviewing those line
4 5	A. None that I can name, but I know that there were some then as well. Q. Sitting here today, can you name	3 4 5	THE WITNESS: No, the system would have been reviewing those line items, but it would have been stopping
4 5 6	A. None that I can name, but I know that there were some then as well. Q. Sitting here today, can you name one?	3 4 5 6	THE WITNESS: No, the system would have been reviewing those line items, but it would have been stopping the orders based on quantity, and then
4 5 6 7	A. None that I can name, but I know that there were some then as well. Q. Sitting here today, can you name one? A. I cannot.	3 4 5 6 7	THE WITNESS: No, the system would have been reviewing those line items, but it would have been stopping the orders based on quantity, and then after quantity, after the orders stopped
4 5 6 7 8	A. None that I can name, but I know that there were some then as well. Q. Sitting here today, can you name one? A. I cannot. Q. It states that there was "no	3 4 5 6 7 8	THE WITNESS: No, the system would have been reviewing those line items, but it would have been stopping the orders based on quantity, and then after quantity, after the orders stopped based on quantity, it would have been
4 5 6 7 8 9	A. None that I can name, but I know that there were some then as well. Q. Sitting here today, can you name one? A. I cannot. Q. It states that there was "no separate/unbiased check of order quantity	3 4 5 6 7 8 9	THE WITNESS: No, the system would have been reviewing those line items, but it would have been stopping the orders based on quantity, and then after quantity, after the orders stopped based on quantity, it would have been reviewed for pattern and frequency.
4 5 6 7 8 9	A. None that I can name, but I know that there were some then as well. Q. Sitting here today, can you name one? A. I cannot. Q. It states that there was "no separate/unbiased check of order quantity outside of the sales and marketing departments."	3 4 5 6 7 8 9	THE WITNESS: No, the system would have been reviewing those line items, but it would have been stopping the orders based on quantity, and then after quantity, after the orders stopped based on quantity, it would have been reviewed for pattern and frequency. BY MR. BUCHANAN:
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. None that I can name, but I know that there were some then as well. Q. Sitting here today, can you name one? A. I cannot. Q. It states that there was "no separate/unbiased check of order quantity outside of the sales and marketing departments." Do you see that? A. Yes. Q. There was no unbiased check of the orders outside of the sales and marketing group, that was an issue with the current process as of October 2014, correct, ma'am – 2013, correct? MS. VANNI: Object to form.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	THE WITNESS: No, the system would have been reviewing those line items, but it would have been stopping the orders based on quantity, and then after quantity, after the orders stopped based on quantity, it would have been reviewed for pattern and frequency. BY MR. BUCHANAN: Q. Okay. Well, we know as of this point in time, certainly what's stated here is there was no check for order frequency and pattern discrepancy, that's what was written by your colleagues in the DEA compliance group, correct? A. By the electronic system. Q. That does not say that; can we
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. None that I can name, but I know that there were some then as well. Q. Sitting here today, can you name one? A. I cannot. Q. It states that there was "no separate/unbiased check of order quantity outside of the sales and marketing departments." Do you see that? A. Yes. Q. There was no unbiased check of the orders outside of the sales and marketing group, that was an issue with the current process as of October 2014, correct, ma'am2013, correct? MS. VANNI: Object to form. THE WITNESS: I'm not quite sure what that bullet means actually at this point, but that's what it says, yes.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	THE WITNESS: No, the system would have been reviewing those line items, but it would have been stopping the orders based on quantity, and then after quantity, after the orders stopped based on quantity, it would have been reviewed for pattern and frequency. BY MR. BUCHANAN: Q. Okay. Well, we know as of this point in time, certainly what's stated here is there was no check for order frequency and pattern discrepancy, that's what was written by your colleagues in the DEA compliance group, correct? A. By the electronic system. Q. That does not say that; can we agree on that? MS. VANNI: Object to form. THE WITNESS: That's how you're

	Page 302		Page 304
1	doesn't say what you just said?	1	is above the regulation.
2	A. It does not say.	2	Q. Okay. Something a responsible
3	Q. Thank you. It says the "system	3	company should do, right?
4	does not allow for" what?	4	MS. VANNI: Object to form.
5	A. "Know Your Customer."	5	THE WITNESS: Possibly, yes.
6	Q. Okay. And so the "Requirements	6	BY MR. BUCHANAN:
7	for Improvement" are listed on the next page,	7	Q. I mean, you list it as a
8	right?	8	requirement, right?
9	Do you see that?	9	A. Right, another example of
10	A. Yes.	10	something that's not a requirement but that's
11	Q. These are things you have to do,	11	listed, yes.
12	right?	12	Q. Okay. I guess if you're going to
13	MS. VANNI: Object to form.	13	make a promise to maintain effective controls of
14	THE WITNESS: Things we wanted to	14	diversion, you should do whatever you can do to
15	do.	15	make sure these things don't leave the channel
16	BY MR. BUCHANAN:	16	of trade, right?
17	Q. It says requirements, right?	17	MS. VANNI: Object to form.
18	A. Things we want to do. It's a	18	THE WITNESS: Yes.
19	play on words but	19	BY MR. BUCHANAN:
20	Q. Well, okay. What's written here	20	Q. And stay in the closed system,
21	while you're before somebody was sitting in	21	yes?
22	this seat to reinterpret the words was	22	MS. VANNI: Object to form.
23	"Requirements for Improvement," agreed?	23	THE WITNESS: Yes.
24	MS. VANNI: Object to form.	24	BY MR. BUCHANAN:
	Page 303		Page 305
1	THE WITNESS: Yes.		
		1	Q. Thank you.
2		1 2	
2	BY MR. BUCHANAN:		It says, and there's a number of
3	BY MR. BUCHANAN: Q. Thank you.	2	It says, and there's a number of items here, but I'm getting notes that I need to
3 4	BY MR. BUCHANAN: Q. Thank you. The first bullet as a requirement	2 3	It says, and there's a number of
3 4 5	BY MR. BUCHANAN: Q. Thank you. The first bullet as a requirement is a system to look at all class of trades and	2 3 4	It says, and there's a number of items here, but I'm getting notes that I need to move more quickly. Let's head down to the third bullet from the bottom.
3 4 5 6	BY MR. BUCHANAN: Q. Thank you. The first bullet as a requirement is a system to look at all class of trades and customers.	2 3 4 5	It says, and there's a number of items here, but I'm getting notes that I need to move more quickly. Let's head down to the third bullet from the bottom. You see that, requirement for
3 4 5 6 7	BY MR. BUCHANAN: Q. Thank you. The first bullet as a requirement is a system to look at all class of trades and customers. Do you see that?	2 3 4 5 6 7	It says, and there's a number of items here, but I'm getting notes that I need to move more quickly. Let's head down to the third bullet from the bottom. You see that, requirement for improvement, "Access to chargeback data and 3rd
3 4 5 6 7 8	BY MR. BUCHANAN: Q. Thank you. The first bullet as a requirement is a system to look at all class of trades and customers. Do you see that? A. Yes.	2 3 4 5 6	It says, and there's a number of items here, but I'm getting notes that I need to move more quickly. Let's head down to the third bullet from the bottom. You see that, requirement for improvement, "Access to chargeback data and 3rd party data i.e. IMS."
3 4 5 6 7 8	BY MR. BUCHANAN: Q. Thank you. The first bullet as a requirement is a system to look at all class of trades and customers. Do you see that? A. Yes. Q. And the classes of trades and	2 3 4 5 6 7 8	It says, and there's a number of items here, but I'm getting notes that I need to move more quickly. Let's head down to the third bullet from the bottom. You see that, requirement for improvement, "Access to chargeback data and 3rd party data i.e. IMS." Do you see that?
3 4 5 6 7 8 9	BY MR. BUCHANAN: Q. Thank you. The first bullet as a requirement is a system to look at all class of trades and customers. Do you see that? A. Yes. Q. And the classes of trades and customers are wholesalers, distributors,	2 3 4 5 6 7 8 9	It says, and there's a number of items here, but I'm getting notes that I need to move more quickly. Let's head down to the third bullet from the bottom. You see that, requirement for improvement, "Access to chargeback data and 3rd party data i.e. IMS." Do you see that? A. Yes, I do.
3 4 5 6 7 8 9 10	BY MR. BUCHANAN: Q. Thank you. The first bullet as a requirement is a system to look at all class of trades and customers. Do you see that? A. Yes. Q. And the classes of trades and customers are wholesalers, distributors, manufacturers, et cetera, right?	2 3 4 5 6 7 8 9 10	It says, and there's a number of items here, but I'm getting notes that I need to move more quickly. Let's head down to the third bullet from the bottom. You see that, requirement for improvement, "Access to chargeback data and 3rd party data i.e. IMS." Do you see that? A. Yes, I do. Q. Okay. So one of the requirements
3 4 5 6 7 8 9 10 11	BY MR. BUCHANAN: Q. Thank you. The first bullet as a requirement is a system to look at all class of trades and customers. Do you see that? A. Yes. Q. And the classes of trades and customers are wholesalers, distributors, manufacturers, et cetera, right? A. Yes.	2 3 4 5 6 7 8 9 10 11 12	It says, and there's a number of items here, but I'm getting notes that I need to move more quickly. Let's head down to the third bullet from the bottom. You see that, requirement for improvement, "Access to chargeback data and 3rd party data i.e. IMS." Do you see that? A. Yes, I do. Q. Okay. So one of the requirements for improvement was implementing chargeback data
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	Page 306		Page 308
1	start looking at chargeback data, right?	1	particular product lines, right?
2	MS. VANNI: Object to form.	2	MS. VANNI: Object to form.
3	THE WITNESS: It's not a	3	THE WITNESS: It's one piece of a
4	regulation.	4	of an investigation, yes.
5	BY MR. BUCHANAN:	5	BY MR. BUCHANAN:
6	Q. Well, didn't they tell you you	6	Q. Okay. We see in this next page
7	need to do that?	7	I'm sorry 1000 606.18.
8	MS. VANNI: Object to form.	8	We saw a memo from Mr. Rannazzisi
9	THE WITNESS: They said you	9	or to Mr. Rannazzisi relating to your DEA
10	should look at it. There's a difference	10	interaction in March of 2013.
11	between should and must.	11	Do you remember that? Ma'am, I'm
12	BY MR. BUCHANAN:	12	probably confusing you by showing you the page
13	Q. Okay. And you'd agree, ma'am, as	13	first.
14	a company that has been given a permission slip	14	Do you remember we were just
15	by the U.S. government to stamp apparently	15	looking at a memo to Mr. Rannazzisi from the DEA
16	billions of pills every year, that you've got to	16	officer who was at the meeting you were in in
17	act consistent with the terms of that permission	17	March of 2013?
18	slip, right?	18	A. Yes.
19	MS. VANNI: Object to form.	19	Q. Okay. In this presentation, it
20	THE WITNESS: Yes, with the	20	says "DEA's Attempted Elucidation of SOMS
21	regulations.	21	Requirement."
22	BY MR. BUCHANAN:	22	Do you see that?
23	Q. And the law, the statute, right?	23	A. Yes.
24	A. Yes.	24	Q. And this is a 2007 letter from
	11. 165.		Q. That and is a 2007 least from
	Page 307		Page 309
1	Q. Which says you must maintain	1	the DEA to you, correct?
2	effective controls against diversion, right?	2	A. Yes.
3	A. Yes.	3	Q. And you were aware of this
4	Q. Okay. And so one of the tools of	4	document, correct?
5	information one of the classes of information	5	MS. VANNI: Object just
6	available to manufacturers for many of its	6	when you say "you," that's vague and
7	customers is chargeback data, right?	7	ambiguous, and she wasn't at the company
8	A. That's what DEA believes, yes.	8	at the time in 2007.
9	Q. Another category of information	9	BY MR. BUCHANAN:
10	that's available to manufacturers is IMS data,	10	Q. Well, I mean, this is a
11	right?	11	PowerPoint from this is a PowerPoint from
12	A. Yes.	12	2013, correct, ma'am?
13	Q. And using IMS data, you can see	13	A. Yeah, but this is just including,
14	in percentage terms quantities that end user	14	I think, the general letter that DEA sent out to
15	pharmacies might be acquiring, whether they're	15	registrants. I have to read it to see.
16	consistent with national averages, whether	16	Q. Oh, okay. Let me but do you
17	they're above national averages or whether	17	recall that the DEA sent out a letter to
18	they're below, right?	18	registrants in 2007?
19	MS. VANNI: Object to form.	19	A. Yes.
20	THE WITNESS: Yes.	20	Q. You were working at a registrant
21	BY MR. BUCHANAN:	21	at that point in time?
22	Q. And that can raise red flags as	22	A. Yes.
23	to whether a pharmacy, for example, is above	23	Q. I ou got a copy of it willie you
	to whether a pharmacy, for example, is above what you know the national average to be for	23	Q. You got a copy of it while you were at that company, right?

	Page 310		Page 312
1	A. Every entity, so, yes, that's	1	THE VIDEOGRAPHER: Going off the
2	what this is.	2	record. The time now is 2:02 p.m.
3	Q. Okay. So this is a letter from	3	(Brief recess.)
4 .	DEA to the company in 2007 saying you've got	4	(Document marked for
5	obligations, you've got to maintain effective	5	identification as Par-Norton Deposition
6	controls against diversion, you've got to have	6	Exhibit No. 13.)
7	suspicious order monitoring systems, a routine	7	THE VIDEOGRAPHER: We're now
8	threshold is not enough, you've got to do more,	8	going back on the record. The time is
9	right?	9	2:24 p.m.
10	MS. VANNI: Object to form.	10	BY MR. BUCHANAN:
11	THE WITNESS: Yes.	11	Q. Ma'am, I'm passing you over
12	BY MR. BUCHANAN:	12	another exhibit in this 2013 period. This one
13	Q. Okay. And I just was I just	13	is from March of 2013. Looks like it's a
14	wanted to confirm that, you know, you were	14	PowerPoint that you put together for a meeting
15	certainly aware of that letter as of 2013, but	15	you were going to have?
16	it sounds like you were aware of the equivalent	16	A. Mm-hmm.
17	letter from your prior work with other	17	Q. You see March 13, 2013, it's
18	manufacturers, correct?	18	E581, and we've marked it as Exhibit 13 to your
19	A. Yes, yes, I was, mm-hmm.	19	deposition.
20	Q. Okay. So you know the DEA had	20	A. Okay.
21	spoken about this certainly prior to 2013?	21	Q. You forward it to a distribution
22	A. Yes.	22	list Ms. Hudson, Ms. Bigelow I'm sorry
23	Q. And you had obviously had that	23	Mr. Bigelow, Mr. Propst, Sanjay Patel, Margaret
24	sit-down you had with Watson and Anda prior to	24	Richardson, Mike Reiney and Jill Connell, cc'd
	Page 311		Page 313
1	that, right?	1	Sue Dear and Patricia Simmet.
2	A. Yes.	2	You see that?
3	Q. Okay. So this is a letter that's	3	A. Yes.
4	being called out to the attention of in the	4	Q. Slide deck for this morning's
5	PowerPoint from 2007 from Mr. Rannazzisi.	5	meeting, right?
6	Then you also identify examples	6	A. Mm-hmm.
7	of repercussions.	7	Q. Is this your group and people
8	Do you see that?	8	that are in management either aligned with your
9	A. Yes.	9	group or they could be affected by what you're
10	Q. And this is again was this	10	being what you're proposing?
11	part of trying to get that kind of management	11	A. It's not my group, it's the
12	buy-in to whether it was increase head count	12	management team.
13	or increase budget to improve the SOM system?	13	Q. I see. This was
14	MS. VANNI: Object to form.	14	A. Some of the management team.
15	THE WITNESS: And education, yes.	15	Q. So this is some folks from your
16	MS. VANNI: Counsel, when you get	16	group and some folks from the management team?
17	a normal stopping break, can we just	17	A. Yes.
18	have a break, use the ladies room.	18	Q. Or just the management team?
19	MR. BUCHANAN: That's fine. I	19	A. When you say "my group," my boss
20	may be just about done with this	20	and boss's boss, yes.
21	document.	21	Q. Okay. But not those who worked
22	MS. VANNI: That's fine.	22	for you?
23	MR. BUCHANAN: It's good. We can	23	A. Correct.
24	go off the record.	24	Q. Understood.
			•

	Page 314		Page 316
1	So this is kind of a high level	1	Reporting," right?
2	deck, right?	2	A. Correct.
3	MS. VANNI: Object to form.	3	Q. Another is "Manufacturing Site
4	THE WITNESS: Yes.	4	Compliance," right?
5	BY MR. BUCHANAN:	5	A. Yes.
6	Q. High level meeting?	6	Q. This is vaults and fences and
7	A. Mm-hmm.	7	monitors and making sure two people are watching
8	Q. That's yes?	8	at all times, that type of stuff?
9	A. Yes.	9	MS. VANNI: Object to form.
10	MS. VANNI: I'll objection to	10	THE WITNESS: Yes.
11	form.	11	BY MR. BUCHANAN:
12	BY MR. BUCHANAN:	12	Q. There's this "Quota Grant
13	Q. So after you get back from the	13	Process" on the left, top left, do you see that?
14	DEA in March of 2013, we saw your e-mail where	14	That's a component of DEA
15	you did some quick thoughts, we've seen the	15	compliance, right?
16	DEA's kind of summary of that meeting and	16	A. Yes, it is.
17	Ms. Hudson's summary of that meeting.	17	Q. Okay. Making sure that you're
18	You recall us discussing that	18	only asking what you need for legitimate medical
19	today?	19	purposes, right?
20	A. Yes.	20	MS. VANNI: Object to form.
21	Q. Okay. And this is your	21	THE WITNESS: Correct.
22	PowerPoint that you put together for the	22	BY MR. BUCHANAN:
23	management team, right?	23	Q. And because, frankly, your quotas
24	A. Yes.	24	are supposed to be based on what's needed for
	1. 105.		are supposed to be based on what's needed for
	Page 315		Page 317
1	Q. Okay. And DEA SOMS action plan,	1	legitimate medical use, right?
2	right?	2	MS. VANNI: Object to form.
3	A. Mm-hmm.	3	THE WITNESS: Yes.
4	Q. March 13, 2013?	4	BY MR. BUCHANAN:
5	A. Yes.	5	Q. Okay. And then there's this
6	Q. And this was something you put	6	component off to the right, as a critical
7	together?	7	element of DEA compliance "Suspicious Order
8	A. Yes, Sanjay had some input into	8	Monitoring," correct?
9	it as well, my boss.	9	A. Correct.
	O Your boss did okay		O So
10	Q. Your boss did, okay. Was your boss at the meeting?	10	Q. So A Excuse me May Liust go back to
10 11	Was your boss at the meeting?	10 11	A. Excuse me. May I just go back to
10 11 12	Was your boss at the meeting? A. At the DEA meeting, I think he	10 11 12	A. Excuse me. May I just go back to the quota process?
10 11 12 13	Was your boss at the meeting? A. At the DEA meeting, I think he he was not, but I think he was supposed to be	10 11 12 13	A. Excuse me. May I just go back to the quota process? Q. If I could move forward, I am
10 11 12 13 14	Was your boss at the meeting? A. At the DEA meeting, I think he he was not, but I think he was supposed to be originally. I think he was missed because of	10 11 12 13 14	A. Excuse me. May I just go back to the quota process? Q. If I could move forward, I am time limited. If it's important enough, feel
10 11 12 13 14 15	Was your boss at the meeting? A. At the DEA meeting, I think he he was not, but I think he was supposed to be originally. I think he was missed because of the snow.	10 11 12 13 14 15	A. Excuse me. May I just go back to the quota process? Q. If I could move forward, I am time limited. If it's important enough, feel free to discuss with your counsel, and she'll
10 11 12 13 14 15	Was your boss at the meeting? A. At the DEA meeting, I think he he was not, but I think he was supposed to be originally. I think he was missed because of the snow. Q. Okay. And on this slide it says	10 11 12 13 14 15 16	A. Excuse me. May I just go back to the quota process? Q. If I could move forward, I am time limited. If it's important enough, feel free to discuss with your counsel, and she'll call it out on direct.
10 11 12 13 14 15 16	Was your boss at the meeting? A. At the DEA meeting, I think he he was not, but I think he was supposed to be originally. I think he was missed because of the snow. Q. Okay. And on this slide it says "Core Elements of DEA Compliance Team," and then	10 11 12 13 14 15 16 17	A. Excuse me. May I just go back to the quota process? Q. If I could move forward, I am time limited. If it's important enough, feel free to discuss with your counsel, and she'll call it out on direct. A. Okay.
10 11 12 13 14 15 16 17	Was your boss at the meeting? A. At the DEA meeting, I think he he was not, but I think he was supposed to be originally. I think he was missed because of the snow. Q. Okay. And on this slide it says "Core Elements of DEA Compliance Team," and then there's this kind of chart in the middle, kind	10 11 12 13 14 15 16 17 18	A. Excuse me. May I just go back to the quota process? Q. If I could move forward, I am time limited. If it's important enough, feel free to discuss with your counsel, and she'll call it out on direct. A. Okay. Q. Suspicious order monitoring and
10 11 12 13 14 15 16 17 18	Was your boss at the meeting? A. At the DEA meeting, I think he he was not, but I think he was supposed to be originally. I think he was missed because of the snow. Q. Okay. And on this slide it says "Core Elements of DEA Compliance Team," and then there's this kind of chart in the middle, kind of a working framework for your presentation,	10 11 12 13 14 15 16 17 18	A. Excuse me. May I just go back to the quota process? Q. If I could move forward, I am time limited. If it's important enough, feel free to discuss with your counsel, and she'll call it out on direct. A. Okay. Q. Suspicious order monitoring and we've spent some time talking about that today,
10 11 12 13 14 15 16 17 18 19	Was your boss at the meeting? A. At the DEA meeting, I think he he was not, but I think he was supposed to be originally. I think he was missed because of the snow. Q. Okay. And on this slide it says "Core Elements of DEA Compliance Team," and then there's this kind of chart in the middle, kind of a working framework for your presentation, "Critical Elements of DEA Compliance."	10 11 12 13 14 15 16 17 18 19 20	A. Excuse me. May I just go back to the quota process? Q. If I could move forward, I am time limited. If it's important enough, feel free to discuss with your counsel, and she'll call it out on direct. A. Okay. Q. Suspicious order monitoring and we've spent some time talking about that today, right?
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10 11 12 13 14 15 16 17 18 19 20 21	Was your boss at the meeting? A. At the DEA meeting, I think he he was not, but I think he was supposed to be originally. I think he was missed because of the snow. Q. Okay. And on this slide it says "Core Elements of DEA Compliance Team," and then there's this kind of chart in the middle, kind of a working framework for your presentation, "Critical Elements of DEA Compliance." Do you see that?	10 11 12 13 14 15 16 17 18 19 20 21	A. Excuse me. May I just go back to the quota process? Q. If I could move forward, I am time limited. If it's important enough, feel free to discuss with your counsel, and she'll call it out on direct. A. Okay. Q. Suspicious order monitoring and we've spent some time talking about that today, right? A. Yes.

_		1	_
	Page 318		Page 320
1	suspicious orders based on unusual size, order	1	Q. And that was one of your
2	pattern, deviation and unusual frequency,"	2	takeaways from this meeting with the DEA, right?
3	correct?	3	MS. VANNI: Object to form.
4	A. That's what it says, yes.	4	THE WITNESS: Yes, it was one of
5	Q. And then the DEA SOMS feedback	5	their feedback points.
6	you got on the next page, 581.6, was that "You	6	BY MR. BUCHANAN:
7	need to differentiate between the sales team	7	Q. And the reference to you there,
8	role and the DEA compliance role", right?	8	as you're kind of rephrasing and recasting what
9	A. Yes, that's what it says.	9	happened at the DEA meeting, was Qualitest,
10	Q. "You need to visit your	10	Qualitest needs to use the chargeback data to
11	customers," right, and then this is an	11	understand what Qualitest customers' customers
12	exclamation point, right?	12	are doing, right?
13	MS. VANNI: Object to form.	13	MS. VANNI: Object to form.
14	THE WITNESS: That's what it	14	THE WITNESS: Yes, that was a
15	says, yes.	15	suggestion by DEA, yes.
16	BY MR. BUCHANAN:	16	BY MR. BUCHANAN:
17	Q. You got to put boots on the	17	Q. And the way you framed it is you
18	ground from compliance with customers, right?	18	need to, right?
19	MS. VANNI: Object to form.	19	A. I'm just documenting what DEA
20	THE WITNESS: Yes, that's what	20	told us during the meeting.
21	DEA would like to see.	21	Q. Right.
22	BY MR. BUCHANAN:	22	And in terms of further
23	Q. I'm assuming you put an	23	documenting what the DEA told you, the DEA told
24	exclamation point in there for emphasis, right?	24	you you must know the customers you are selling
	r		y y
	Page 319		Page 321
1	A. Yes.	1	to, right?
2	Q. Okay. We have a problem, I guess	2	A. Yes.
3	"we" there is the DEA are you using we to	3	Q. "You need to track your product
4	refer to the DEA?	4	from the time it is manufactured to when it is
5	A. We to refer to our company.	5	sold to the patient."
6	Q. Well, it says, we have a problem	6	Did I read that correctly?
7	with companies using their sales team to conduct	7	A. To the best of your ability.
8	these site visits.	8	Yes, you did read it correctly.
9	A. Oh, I'm sorry, it is DEA.	9	Q. The way you wrote it was, and you
10	Q. In that instance, you were using	10	didn't put to the best of your ability, but the
11	the term we to refer to the DEA?	11	way you wrote it was you need to track your
12	A. Yes.	12	product from the time it is manufactured to when
13	Q. Right, and you understood the DEA	13	it is sold to the patient, correct?
14	had a problem with companies using sales teams	14	MS. VANNI: Object to form.
15	to conduct the site visits, right?	15	THE WITNESS: Yes, that's how
16	MS. VANNI: Object to form.	16	it's written.
17	THE WITNESS: They had a concern,	17	BY MR. BUCHANAN:
18	yes.	18	Q. "Need to have the best possible
19	BY MR. BUCHANAN:	19	systems to know what is happening with your
20	Q. Then it says you need to use the	20	product," right?
21	chargeback data to understand what your	21	A. That's what it says, yes.
22	customers' customers are doing.	22	Q. That's what you wrote.
23	Did I read that correctly?	23	And this was your DEA feedback
24	A. Yes.	24	that you were recounting to senior management at
			<u> </u>

	Page 322		Page 324
1	Qualitest, correct?	1	right?
2	MS. VANNI: Object to form.	2	A. Yes, that's what it says.
3	THE WITNESS: Correct.	3	Q. That's what you wrote?
4 .	BY MR. BUCHANAN:	4	A. Yes. It's all things that DEA
5	Q. You "need to have a good SOM	5	commented on or suggested during their meeting.
6	program that is adequate for the business you	6	Q. Right. I mean, all things that
7	are in," right?	7	you thought were important enough to relay to
8	A. Yes, that's what it says.	8	senior management, correct?
9	Q. Okay. Then says "look at the	9	MS. VANNI: Object to form.
10	charts provided," and I guess you're saying that	10	THE WITNESS: Yes.
11	was what the DEA told you, look at the charts	11	BY MR. BUCHANAN:
12	provided, right?	12	Q. Okay. Further, that "You need to
13	A. Yes.	13	visit your customer's customers and document
14	Q. Remember we looked at those	14	your findings," right?
15	graphs that had vintage and Generic Bidco, I	15	A. Yes.
16	think was the other one?	16	Q. That's what it says?
17	A. Yes, we did.	17	A. That's what it says.
18	Q. Okay. Those were the charts you	18	Q. Not just your customers, right?
19	got from the DEA?	19	A. It says "your customer's
20	A. Yes.	20	customers."
21	Q. All right. And so you're saying	21	Q. Right. So you need to visit not
22	the DEA told you to look at the charts provided	22	just your customers but your customers'
23	and we will visit your site and we will want to	23	customers, right?
24		24	MS. VANNI: Object to form.
24	see improvements in when?	24	MS. VAINNI. Object to form.
	Page 323		Page 325
1	A. In six months.	1	THE WITNESS, W
2		_	THE WITNESS: Yes.
_	Q. Right. In six months.	2	BY MR. BUCHANAN:
3	Q. Right. In six months. So we've been looking at some		BY MR. BUCHANAN:
	So we've been looking at some	2	BY MR. BUCHANAN: Q. And document your findings; is
3	So we've been looking at some dialogue that was happening in October,	2 3	BY MR. BUCHANAN: Q. And document your findings; is that right?
3 4 5	So we've been looking at some dialogue that was happening in October, September of 2013.	2 3 4	BY MR. BUCHANAN: Q. And document your findings; is that right?
3 4	So we've been looking at some dialogue that was happening in October, September of 2013. You recall that?	2 3 4 5	BY MR. BUCHANAN: Q. And document your findings; is that right? A. Yes, which would not be permitted.
3 4 5 6 7	So we've been looking at some dialogue that was happening in October, September of 2013. You recall that? A. Yes.	2 3 4 5 6 7	BY MR. BUCHANAN: Q. And document your findings; is that right? A. Yes, which would not be permitted. Q. And you I'm sorry?
3 4 5 6 7 8	So we've been looking at some dialogue that was happening in October, September of 2013. You recall that? A. Yes. Q. You brought Mr. Brantley in in	2 3 4 5 6 7 8	BY MR. BUCHANAN: Q. And document your findings; is that right? A. Yes, which would not be permitted. Q. And you I'm sorry? A. Which would not be permitted.
3 4 5 6 7 8	So we've been looking at some dialogue that was happening in October, September of 2013. You recall that? A. Yes. Q. You brought Mr. Brantley in in September of 2013, roughly about six months	2 3 4 5 6 7 8	BY MR. BUCHANAN: Q. And document your findings; is that right? A. Yes, which would not be permitted. Q. And you I'm sorry? A. Which would not be permitted. You can't visit your customers' customers.
3 4 5 6 7 8 9	So we've been looking at some dialogue that was happening in October, September of 2013. You recall that? A. Yes. Q. You brought Mr. Brantley in in September of 2013, roughly about six months after this, right?	2 3 4 5 6 7 8 9	BY MR. BUCHANAN: Q. And document your findings; is that right? A. Yes, which would not be permitted. Q. And you I'm sorry? A. Which would not be permitted. You can't visit your customers' customers. They're not your customer.
3 4 5 6 7 8 9 10	So we've been looking at some dialogue that was happening in October, September of 2013. You recall that? A. Yes. Q. You brought Mr. Brantley in in September of 2013, roughly about six months after this, right? A. Yes.	2 3 4 5 6 7 8 9 10	BY MR. BUCHANAN: Q. And document your findings; is that right? A. Yes, which would not be permitted. Q. And you I'm sorry? A. Which would not be permitted. You can't visit your customers' customers. They're not your customer. Q. You can go to any pharmacy you
3 4 5 6 7 8 9 10 11	So we've been looking at some dialogue that was happening in October, September of 2013. You recall that? A. Yes. Q. You brought Mr. Brantley in in September of 2013, roughly about six months after this, right? A. Yes. Q. You sent your dear customer	2 3 4 5 6 7 8 9 10 11 12	BY MR. BUCHANAN: Q. And document your findings; is that right? A. Yes, which would not be permitted. Q. And you I'm sorry? A. Which would not be permitted. You can't visit your customers' customers. They're not your customer. Q. You can go to any pharmacy you want and walk into, right?
3 4 5 6 7 8 9 10 11 12 13	So we've been looking at some dialogue that was happening in October, September of 2013. You recall that? A. Yes. Q. You brought Mr. Brantley in in September of 2013, roughly about six months after this, right? A. Yes. Q. You sent your dear customer letter out in mid-October of 2013, right?	2 3 4 5 6 7 8 9 10 11 12 13	BY MR. BUCHANAN: Q. And document your findings; is that right? A. Yes, which would not be permitted. Q. And you I'm sorry? A. Which would not be permitted. You can't visit your customers' customers. They're not your customer. Q. You can go to any pharmacy you want and walk into, right? A. Not to do a SOM visit, not to ask
3 4 5 6 7 8 9 10 11 12 13 14	So we've been looking at some dialogue that was happening in October, September of 2013. You recall that? A. Yes. Q. You brought Mr. Brantley in in September of 2013, roughly about six months after this, right? A. Yes. Q. You sent your dear customer letter out in mid-October of 2013, right? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14	BY MR. BUCHANAN: Q. And document your findings; is that right? A. Yes, which would not be permitted. Q. And you I'm sorry? A. Which would not be permitted. You can't visit your customers' customers. They're not your customer. Q. You can go to any pharmacy you want and walk into, right? A. Not to do a SOM visit, not to ask questions about their business and their
3 4 5 6 7 8 9 10 11 12 13 14 15	So we've been looking at some dialogue that was happening in October, September of 2013. You recall that? A. Yes. Q. You brought Mr. Brantley in in September of 2013, roughly about six months after this, right? A. Yes. Q. You sent your dear customer letter out in mid-October of 2013, right? A. Yes. Q. And you sat down with the DEA	2 3 4 5 6 7 8 9 10 11 12 13 14	BY MR. BUCHANAN: Q. And document your findings; is that right? A. Yes, which would not be permitted. Q. And you I'm sorry? A. Which would not be permitted. You can't visit your customers' customers. They're not your customer. Q. You can go to any pharmacy you want and walk into, right? A. Not to do a SOM visit, not to ask questions about their business and their program. That's your customer's job to ask
3 4 5 6 7 8 9 10 11 12 13 14 15 16	So we've been looking at some dialogue that was happening in October, September of 2013. You recall that? A. Yes. Q. You brought Mr. Brantley in in September of 2013, roughly about six months after this, right? A. Yes. Q. You sent your dear customer letter out in mid-October of 2013, right? A. Yes. Q. And you sat down with the DEA again couple weeks after your dear customer	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	BY MR. BUCHANAN: Q. And document your findings; is that right? A. Yes, which would not be permitted. Q. And you I'm sorry? A. Which would not be permitted. You can't visit your customers' customers. They're not your customer. Q. You can go to any pharmacy you want and walk into, right? A. Not to do a SOM visit, not to ask questions about their business and their program. That's your customer's job to ask questions about their customer. So you can't
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	So we've been looking at some dialogue that was happening in October, September of 2013. You recall that? A. Yes. Q. You brought Mr. Brantley in in September of 2013, roughly about six months after this, right? A. Yes. Q. You sent your dear customer letter out in mid-October of 2013, right? A. Yes. Q. And you sat down with the DEA again couple weeks after your dear customer letter went out, right?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	BY MR. BUCHANAN: Q. And document your findings; is that right? A. Yes, which would not be permitted. Q. And you I'm sorry? A. Which would not be permitted. You can't visit your customers' customers. They're not your customer. Q. You can go to any pharmacy you want and walk into, right? A. Not to do a SOM visit, not to ask questions about their business and their program. That's your customer's job to ask questions about their customer. So you can't skip a line a link in the supply chain and go
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	So we've been looking at some dialogue that was happening in October, September of 2013. You recall that? A. Yes. Q. You brought Mr. Brantley in in September of 2013, roughly about six months after this, right? A. Yes. Q. You sent your dear customer letter out in mid-October of 2013, right? A. Yes. Q. And you sat down with the DEA again couple weeks after your dear customer letter went out, right? MS. VANNI: Object to form.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	BY MR. BUCHANAN: Q. And document your findings; is that right? A. Yes, which would not be permitted. Q. And you I'm sorry? A. Which would not be permitted. You can't visit your customers' customers. They're not your customer. Q. You can go to any pharmacy you want and walk into, right? A. Not to do a SOM visit, not to ask questions about their business and their program. That's your customer's job to ask questions about their customer. So you can't skip a line a link in the supply chain and go to that next level
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	So we've been looking at some dialogue that was happening in October, September of 2013. You recall that? A. Yes. Q. You brought Mr. Brantley in in September of 2013, roughly about six months after this, right? A. Yes. Q. You sent your dear customer letter out in mid-October of 2013, right? A. Yes. Q. And you sat down with the DEA again couple weeks after your dear customer letter went out, right? MS. VANNI: Object to form. THE WITNESS: Yes, I believe so.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	BY MR. BUCHANAN: Q. And document your findings; is that right? A. Yes, which would not be permitted. Q. And you I'm sorry? A. Which would not be permitted. You can't visit your customers' customers. They're not your customer. Q. You can go to any pharmacy you want and walk into, right? A. Not to do a SOM visit, not to ask questions about their business and their program. That's your customer's job to ask questions about their customer. So you can't skip a line a link in the supply chain and go to that next level Q. Well, we can agree you didn't
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	So we've been looking at some dialogue that was happening in October, September of 2013. You recall that? A. Yes. Q. You brought Mr. Brantley in in September of 2013, roughly about six months after this, right? A. Yes. Q. You sent your dear customer letter out in mid-October of 2013, right? A. Yes. Q. And you sat down with the DEA again couple weeks after your dear customer letter went out, right? MS. VANNI: Object to form. THE WITNESS: Yes, I believe so. BY MR. BUCHANAN:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	BY MR. BUCHANAN: Q. And document your findings; is that right? A. Yes, which would not be permitted. Q. And you — I'm sorry? A. Which would not be permitted. You can't visit your customers' customers. They're not your customer. Q. You can go to any pharmacy you want and walk into, right? A. Not to do a SOM visit, not to ask questions about their business and their program. That's your customer's job to ask questions about their customer. So you can't skip a line — a link in the supply chain and go to that next level — Q. Well, we can agree you didn't tell the DEA that in March 2013, did you, ma'am?
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	So we've been looking at some dialogue that was happening in October, September of 2013. You recall that? A. Yes. Q. You brought Mr. Brantley in in September of 2013, roughly about six months after this, right? A. Yes. Q. You sent your dear customer letter out in mid-October of 2013, right? A. Yes. Q. And you sat down with the DEA again couple weeks after your dear customer letter went out, right? MS. VANNI: Object to form. THE WITNESS: Yes, I believe so. BY MR. BUCHANAN: Q. Okay. "We will not look the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY MR. BUCHANAN: Q. And document your findings; is that right? A. Yes, which would not be permitted. Q. And you I'm sorry? A. Which would not be permitted. You can't visit your customers' customers. They're not your customer. Q. You can go to any pharmacy you want and walk into, right? A. Not to do a SOM visit, not to ask questions about their business and their program. That's your customer's job to ask questions about their customer. So you can't skip a line a link in the supply chain and go to that next level Q. Well, we can agree you didn't tell the DEA that in March 2013, did you, ma'am? MS. VANNI: Object to form.
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	So we've been looking at some dialogue that was happening in October, September of 2013. You recall that? A. Yes. Q. You brought Mr. Brantley in in September of 2013, roughly about six months after this, right? A. Yes. Q. You sent your dear customer letter out in mid-October of 2013, right? A. Yes. Q. And you sat down with the DEA again couple weeks after your dear customer letter went out, right? MS. VANNI: Object to form. THE WITNESS: Yes, I believe so. BY MR. BUCHANAN: Q. Okay. "We will not look the other way if someone screws up. Possible	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MR. BUCHANAN: Q. And document your findings; is that right? A. Yes, which would not be permitted. Q. And you I'm sorry? A. Which would not be permitted. You can't visit your customers' customers. They're not your customer. Q. You can go to any pharmacy you want and walk into, right? A. Not to do a SOM visit, not to ask questions about their business and their program. That's your customer's job to ask questions about their customer. So you can't skip a line a link in the supply chain and go to that next level Q. Well, we can agree you didn't tell the DEA that in March 2013, did you, ma'am? MS. VANNI: Object to form. THE WITNESS: We didn't get into
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	So we've been looking at some dialogue that was happening in October, September of 2013. You recall that? A. Yes. Q. You brought Mr. Brantley in in September of 2013, roughly about six months after this, right? A. Yes. Q. You sent your dear customer letter out in mid-October of 2013, right? A. Yes. Q. And you sat down with the DEA again couple weeks after your dear customer letter went out, right? MS. VANNI: Object to form. THE WITNESS: Yes, I believe so. BY MR. BUCHANAN: Q. Okay. "We will not look the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY MR. BUCHANAN: Q. And document your findings; is that right? A. Yes, which would not be permitted. Q. And you I'm sorry? A. Which would not be permitted. You can't visit your customers' customers. They're not your customer. Q. You can go to any pharmacy you want and walk into, right? A. Not to do a SOM visit, not to ask questions about their business and their program. That's your customer's job to ask questions about their customer. So you can't skip a line a link in the supply chain and go to that next level Q. Well, we can agree you didn't tell the DEA that in March 2013, did you, ma'am? MS. VANNI: Object to form.

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1	BY MR. BUCHANAN:	1	received, right, "you cannot sell," correct?
2	Q. Right, and what the	2	MS. VANNI: Object to the form.
3	A. We were more listening.	3	THE WITNESS: That was the
4	Q. What the DEA told you was you	4	feedback we received, yes.
5	need to visit your customers' customers and	5	BY MR. BUCHANAN:
6	document your findings, right?	6	Q. You must alert us of suspicious
7	A. That's what the document says,	7	orders, right?
8	yes.	8	A. Yes.
9	Q. And "you must provide documented	9	Q. And if you don't adhere to your
10	evidence of these assessments," right?	10	responsibilities, and, again, everything that
11	A. Yes, and, again, none of this is	11	we've just identified was information you
12	in the regulations.	12	received from DEA at that meeting, right?
13	Q. Ma'am, just stay with my	13	A. Yes.
14	questions, okay.	14	Q. And here you say, "If you fail to
15	A. Yes.	15	adhere to your responsibilities," you understood
16	Q. We could agree this is what you	16	these to be your responsibilities, right?
17	were told to do, correct?	17	MS. VANNI: Object to the form.
18	MS. VANNI: Object to the form.	18	THE WITNESS: It's your
19	THE WITNESS: This is these	19	responsibility to comply to the
20	are the suggestions we received, the	20	regulation.
21	feedback we received at that meeting.	21	BY MR. BUCHANAN:
22	BY MR. BUCHANAN:	22	Q. What you wrote here is, "If you
23	Q. Well, you're saying suggestions.	23	fail to adhere to your responsibilities," and we
24	It says you need to, right?	24	could agree that above that is one, two, three,
	Page 327		Page 329
	-		- 5
1	A. If we needed to, there would have	1	four, five, six, seven, eight, nine items, and
2		1 2	four, five, six, seven, eight, nine items, and the jury will have the document, but there's
	A. If we needed to, there would have		four, five, six, seven, eight, nine items, and
2	A. If we needed to, there would have been a violation coming as a result of not	2	four, five, six, seven, eight, nine items, and the jury will have the document, but there's nine items where you identified you need to, we must, you need to, you must know, you need to
2 3	A. If we needed to, there would have been a violation coming as a result of not having it.	2 3	four, five, six, seven, eight, nine items, and the jury will have the document, but there's nine items where you identified you need to, we must, you need to, you must know, you need to have the best possible, you need to have a good
2 3 4	A. If we needed to, there would have been a violation coming as a result of not having it. Q. Well, let's not recast. How did	2 3 4	four, five, six, seven, eight, nine items, and the jury will have the document, but there's nine items where you identified you need to, we must, you need to, you must know, you need to have the best possible, you need to have a good SOM program, we will visit your site to confirm
2 3 4 5	A. If we needed to, there would have been a violation coming as a result of not having it. Q. Well, let's not recast. How did you write it? MS. VANNI: Object to the colloquy.	2 3 4 5	four, five, six, seven, eight, nine items, and the jury will have the document, but there's nine items where you identified you need to, we must, you need to, you must know, you need to have the best possible, you need to have a good
2 3 4 5 6	A. If we needed to, there would have been a violation coming as a result of not having it. Q. Well, let's not recast. How did you write it? MS. VANNI: Object to the	2 3 4 5 6	four, five, six, seven, eight, nine items, and the jury will have the document, but there's nine items where you identified you need to, we must, you need to, you must know, you need to have the best possible, you need to have a good SOM program, we will visit your site to confirm improvements, we will not look the other way, you need to visit, need, need,
2 3 4 5 6 7	A. If we needed to, there would have been a violation coming as a result of not having it. Q. Well, let's not recast. How did you write it? MS. VANNI: Object to the colloquy.	2 3 4 5 6 7	four, five, six, seven, eight, nine items, and the jury will have the document, but there's nine items where you identified you need to, we must, you need to, you must know, you need to have the best possible, you need to have a good SOM program, we will visit your site to confirm improvements, we will not look the other way, you need to visit, need, need, need, requirements, right?
2 3 4 5 6 7 8 9	A. If we needed to, there would have been a violation coming as a result of not having it. Q. Well, let's not recast. How did you write it? MS. VANNI: Object to the colloquy. THE WITNESS: It's written as the feedback that we received from the DEA. BY MR. BUCHANAN:	2 3 4 5 6 7 8 9	four, five, six, seven, eight, nine items, and the jury will have the document, but there's nine items where you identified you need to, we must, you need to, you must know, you need to have the best possible, you need to have a good SOM program, we will visit your site to confirm improvements, we will not look the other way, you need to visit, need, need, requirements, right? MS. VANNI: Object to form.
2 3 4 5 6 7 8 9 10	A. If we needed to, there would have been a violation coming as a result of not having it. Q. Well, let's not recast. How did you write it? MS. VANNI: Object to the colloquy. THE WITNESS: It's written as the feedback that we received from the DEA. BY MR. BUCHANAN: Q. Let's stay on this bullet, ma'am.	2 3 4 5 6 7 8 9 10	four, five, six, seven, eight, nine items, and the jury will have the document, but there's nine items where you identified you need to, we must, you need to, you must know, you need to have the best possible, you need to have a good SOM program, we will visit your site to confirm improvements, we will not look the other way, you need to visit, need, need, requirements, right? MS. VANNI: Object to form. THE WITNESS: These are all
2 3 4 5 6 7 8 9	A. If we needed to, there would have been a violation coming as a result of not having it. Q. Well, let's not recast. How did you write it? MS. VANNI: Object to the colloquy. THE WITNESS: It's written as the feedback that we received from the DEA. BY MR. BUCHANAN: Q. Let's stay on this bullet, ma'am. What did you write, "you need to"?	2 3 4 5 6 7 8 9 10 11 12	four, five, six, seven, eight, nine items, and the jury will have the document, but there's nine items where you identified you need to, we must, you need to, you must know, you need to have the best possible, you need to have a good SOM program, we will visit your site to confirm improvements, we will not look the other way, you need to visit, need, need, need, requirements, right? MS. VANNI: Object to form. THE WITNESS: These are all things that DEA suggested during the
2 3 4 5 6 7 8 9 10 11 12 13	A. If we needed to, there would have been a violation coming as a result of not having it. Q. Well, let's not recast. How did you write it? MS. VANNI: Object to the colloquy. THE WITNESS: It's written as the feedback that we received from the DEA. BY MR. BUCHANAN: Q. Let's stay on this bullet, ma'am. What did you write, "you need to"? A. "You need to visit your	2 3 4 5 6 7 8 9 10 11 12 13	four, five, six, seven, eight, nine items, and the jury will have the document, but there's nine items where you identified you need to, we must, you need to, you must know, you need to have the best possible, you need to have a good SOM program, we will visit your site to confirm improvements, we will not look the other way, you need to visit, need, need, requirements, right? MS. VANNI: Object to form. THE WITNESS: These are all things that DEA suggested during the meeting.
2 3 4 5 6 7 8 9 10 11 12 13 14	A. If we needed to, there would have been a violation coming as a result of not having it. Q. Well, let's not recast. How did you write it? MS. VANNI: Object to the colloquy. THE WITNESS: It's written as the feedback that we received from the DEA. BY MR. BUCHANAN: Q. Let's stay on this bullet, ma'am. What did you write, "you need to"? A. "You need to visit your customer's customers and document your	2 3 4 5 6 7 8 9 10 11 12 13 14	four, five, six, seven, eight, nine items, and the jury will have the document, but there's nine items where you identified you need to, we must, you need to, you must know, you need to have the best possible, you need to have a good SOM program, we will visit your site to confirm improvements, we will not look the other way, you need to visit, need, need, requirements, right? MS. VANNI: Object to form. THE WITNESS: These are all things that DEA suggested during the meeting. BY MR. BUCHANAN:
2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. If we needed to, there would have been a violation coming as a result of not having it. Q. Well, let's not recast. How did you write it? MS. VANNI: Object to the colloquy. THE WITNESS: It's written as the feedback that we received from the DEA. BY MR. BUCHANAN: Q. Let's stay on this bullet, ma'am. What did you write, "you need to"? A. "You need to visit your customer's customers and document your findings."	2 3 4 5 6 7 8 9 10 11 12 13 14	four, five, six, seven, eight, nine items, and the jury will have the document, but there's nine items where you identified you need to, we must, you need to, you must know, you need to have the best possible, you need to have a good SOM program, we will visit your site to confirm improvements, we will not look the other way, you need to visit, need, need, requirements, right? MS. VANNI: Object to form. THE WITNESS: These are all things that DEA suggested during the meeting. BY MR. BUCHANAN: Q. "If you fail to adhere to your
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. If we needed to, there would have been a violation coming as a result of not having it. Q. Well, let's not recast. How did you write it? MS. VANNI: Object to the colloquy. THE WITNESS: It's written as the feedback that we received from the DEA. BY MR. BUCHANAN: Q. Let's stay on this bullet, ma'am. What did you write, "you need to"? A. "You need to visit your customer's customers and document your findings." Q. Next sentence.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	four, five, six, seven, eight, nine items, and the jury will have the document, but there's nine items where you identified you need to, we must, you need to, you must know, you need to have the best possible, you need to have a good SOM program, we will visit your site to confirm improvements, we will not look the other way, you need to visit, need, need, need, requirements, right? MS. VANNI: Object to form. THE WITNESS: These are all things that DEA suggested during the meeting. BY MR. BUCHANAN: Q. "If you fail to adhere to your responsibilities, you present" what, ma'am?
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2 and visit a facility, if you can't look at chargeback data, I mean, all you can do is you best, right? 3		Page 330		Page 332
2 BY MR. BUCHANAN: 3 Q. To maintain a closed system? 4 A. Yes, and we did. 5 Q. Move to strike, ma'am. Stay with 6 my question. 7 Your obligation, I'm not asking 8 what happened. Somebody cles will decide 9 whether it complied or didn't comply. 10 A. Yes. 11 Q. Your obligation is to maintain 12 that closed system, correct? 13 MS. VANNI: Object to form. 14 THE WITNESS: Yes. 15 BY MR. BUCHANAN: 16 Q. Your obligation in maintaining 17 that closed system is to sell to people who, 18 based on your due diligence and investigation, 19 will likewise maintain that closed system, 10 gript? 21 A. Yes. 22 Q. And to conduct due diligence to 23 assure that their customers have processes in 24 place to maintain the closed system, 25 BY MR. BUCHANAN: 26 Q. It's not a suggestion is 3 to know your customer. The suggestion 4 is not to know your customer is not to know your customers customers. 5 BY MR. BUCHANAN: 6 Q. It's not a suggestion, ma'am. 7 What you took away from that 8 meeting is you must know the customers you're 9 selling to first, right? 10 A. A. Mm-hmm, yes. 11 Q. And we looked at your document 12 earlier today where you recounted it as you must 13 also know your customers' customers, correct? 14 A. Yes, to the best of your ability, when you can. 16 Q. What every reasonable 17 manufacturer should do, right? 18 MR. BUCHANAN: 19 manufacturer should do, right? 19 manufacturer should do, right? 20 MS. VANNI: Object to form. 21 THE WITNESS: If the information 22 is available to you. 23 BY MR. BUCHANAN: 24 and satial, Imean, all you cand to is you best, right? 25 A. Correct. 26 BY MR. BUCHANAN: 27 Day us see that? 28 A. Yes. 29 Q. And to conduct due diligence to 29 distributors." 20 Q. Okay. And something that you thought worthy of — 21 A. Missage. 22 Q. You disagree? 23 You disagree? 24 You disagree? 25 Q. You disagree? 26 You disagree? 27 A. I disagree. 28 Q. Wall, I mean, you'd agree that 29 You have you can. 29 Selling to first, right? 30 You have the drive the form. 31 You have the drugs if it weren't for the manufac	1	regulations and maintain.	1	information can't be discerned, if you can't go
4 A. Yes, and we did. 5 Q. Move to strike, ma'am. Stay with 6 my question. 7 Your obligation, I'm not asking 8 what happened. Somebody else will decide 9 whether it complied or didn't comply. 10 A. Yes. 11 Q. Your obligation is to maintain 12 that closed system, correct? 13 MS. VANNI: Object to form. 14 THE WITNESS: Yes. 15 BY MR. BUCHANAN: 16 Q. Your obligation in maintaining 17 that closed system is to sell to people who, 18 based on your due diligence and investigation, 19 will likewise maintain that closed system, 20 right? 21 A. Yes. 22 Q. And to conduct due diligence to 23 assure that their customers have processes in 24 place to maintain the closed system, correct? 25 assure that their customers have processes in 26 place to maintain the closed system, correct? 27 assure that their customers have processes in 28 place to maintain the closed system, correct? 29 C. And to conduct due diligence to 20 assure that their customers have processes in 21 place to maintain the closed system, correct? 22 place to maintain the closed system, correct? 23 assure that their customers have processes in 24 place to maintain the closed system, correct? 25 place to maintain the closed system, correct? 26 place to maintain the closed system, correct? 27 assure that their customers have processes in 28 place to maintain the closed system, correct? 29 place to maintain the closed system, correct? 20 And to conduct due diligence to 21 assure that their customers have processes in 22 place to maintain the closed system, correct? 23 assure that their customers have processes in 24 place to maintain the closed system, correct? 25 place to maintain the closed system, correct? 26 place to maintain the closed system, correct? 27 and to conduct due diligence to 28 assure that their customers fave processes in 29 place to maintain the closed system, correct? 30 poyou see that? 31 Q. Okay. And something that you thought worthy of	2		2	
5 Q. Move to strike, ma'am. Stay with my question. 6 my question. 7 Your obligation, I'm not asking what happened. Somebody else will decide whether it complied or didn't comply. 10 A. Yes. 11 Q. Your obligation is to maintain that closed system, correct? 13 MS. VANNI: Object to form. 14 THE WITNESS: Yes. 15 BY MR. BUCHANAN: 16 Q. Your obligation in maintaining that closed system is to sell to people who, will likewise maintain that closed system, oright? 17 that closed system is to sell to people who, will likewise maintain that closed system, oright? 18 based on your due diligence and investigation, will likewise maintain that closed system, oright? 19 A. Yes. 20 Q. And to conduct due diligence to again a succept that it customers have processes in place to maintain the closed system, correct? 21 MS. VANNI: Object to form. 22 THE WITNESS: The suggestion is to know your customer. The suggestion is not to know your customer's customer. 3 to know your customer. The suggestion is not to know your customer's customer. 4 MS. VANNI: Object to form. 2 THE WITNESS: The suggestion is to know your customer's customer. 5 MS. VANNI: Object to form. 2 THE WITNESS: The suggestion is so to know your customer's customer. 6 Q. R's not a suggestion, ma'am. 7 What you took away from that meeting is you must know the customers you're selling to first, right? 10 A. Yes, to the best of your ability when you can. 11 Q. The best of your ability when you can. 12 also know your customer's customers, correct? 13 A. Yes, to the best of your ability when you can. 14 A. Yes, to the best of your ability when you can. 15 WMR. BUCHANAN: 16 Q. What every reasonable manufacturer should do, right? 17 A. Yes. 18 Q. What every reasonable manufacturers should do, right? 19 MS. VANNI: Object to form. 20 MS. VANNI: Object to form. 21 THE WITNESS: If the information is that closed system in the closed system in the closed system. 22 The WITNESS: If the information is that closed system is to sell to people who, will wis a discussion with the closed sy	3	Q. To maintain a closed system?	3	chargeback data, I mean, all you can do is your
6 my question. 7 Your obligation, I'm not asking 8 what happened. Somebody else will decide whether it complied or didn't comply. 10 A. Yes. 11 Q. Your obligation is to maintain 12 that closed system, correct? 13 MS. VANNI: Object to form. 14 THE WITNESS: Yes. 15 BY MR. BUCHANAN: 16 Q. Your obligation in maintaining 17 that closed system is to sell to people who, 18 based on your due diligence and investigation, 19 will likewise maintain that closed system, correct? 20 And to conduct due diligence to 23 assure that their customers have processes in 24 place to maintain the closed system, correct? 25 BY MR. BUCHANAN: 26 Q. Your obligation in maintaining 27 that closed system is to sell to people who, 18 based on your due diligence to assure that their customers have processes in 24 place to maintain the closed system, correct? 26 MS. VANNI: Object to form. 27 THE WITNESS: The suggestion is 28 to know your customer. The suggestion is 39 to know your customer. The suggestion is 40 is not to know your customer for suggestion is 51 to know your customer for suggestion is 52 and to conduct due diligence to 53 as to know your customer's customer. 54 BY MR. BUCHANAN: 55 A Disagree. 66 Q. It's not a suggestion, ma'am. 67 What you took away from that 68 meeting is you must know the customers you're 69 selling to first, right? 60 A. Mm-hmm, yes. 61 Q. And we looked at your document 62 aeriler today where you recounted it as you must 63 also know your customers' customers, correct? 64 A. Yes, 65 Q. What were you recounted it as you must 66 Q. What every reasonable 67 MS. VANNI: Object to form. 68 MS. VANNI: Object to form. 79 MR. BUCHANAN: 90 MR. BUCHANAN: 91 MR. BUCHANAN:	4	A. Yes, and we did.	4	best, right?
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What happened. Somebody else will decide whether it complied or didn't comply.	6	my question.	6	Q. But you've got to try to do your
whether it complied or didn't comply. A. Yes. O. Your obligation is to maintain 12 that closed system, correct? 13 MS. VANNI: Object to form. 14 THE WITNESS: Yes. 15 BY MR. BUCHANAN: 16 Q. Your obligation in maintaining 16 that closed system is to sell to people who, 17 based on your due diligence and investigation, 18 based on your due diligence and investigation, 19 will likewise maintain that closed system, 19 right? 20 right? 21 A. Yes. 22 Q. And to conduct due diligence to 23 assure that their customers have processes in 24 place to maintain the closed system, correct? 24 MS. VANNI: Object to form. 25 THE WITNESS: Yes. 26 BY MR. BUCHANAN: 27 D, That was a true statement certainly as of 2013, right? 28 MS. VANNI: Object to form. 29 THE WITNESS: Yes. 29 PAGNANI: Object to form. 20 THE WITNESS: Yes. 21 Pool as a reborn addicted." 20 That was a true statement certainly as of 2013, right? 21 MS. VANNI: Object to form. 22 THE WITNESS: Yes. 24 A. Yes. 25 Q. That was a true statement certainly as of 2013, right? 26 MS. VANNI: Object to form. 27 THE WITNESS: Yes. 28 BY MR. BUCHANAN: 29 THE WITNESS: Yes. 29 A. Yes. 20 Q. That was a true statement certainly as of 2013, right? 20 MS. VANNI: Object to form. 21 MS. VANNI: Object to form. 22 THE WITNESS: Yes. 24 A. Yes. 25 Q. That was a true statement certainly as of 2013, right? 26 MS. VANNI: Object to form. 29 THE WITNESS: Yes. 20 Q. That was a true statement certainly as of 2013, right? 20 MS. VANNI: Object to form. 21 MS. VANNI: Object to form. 22 THE WITNESS: Yes. 24 A. Yes. 25 Q. That was a true statement certainly as of 2013, right? 26 MS. VANNI: Object to form. 27 A. Yes. 28 BY MR. BUCHANAN: 29 Well, Imean, you'd agree that you made 33 billion pills of Vocidin, right? 29 MS. VANNI: Object to form. 20 Well, Imean, you'd agree that you made 33 billion pills of Vocidin, right? 20 MS. VANNI: Objection to form. 21 THE WITNESS: If the information is available to you. 22 Well, Imean, you'd agree that where those numbers came from. 23 BY MR. BUCHANAN: 24 What they vot o	7	Your obligation, I'm not asking	7	best, right?
10 A. Yes. 11 Q. Your obligation is to maintain 12 that closed system, correct? 13 MS. VANNI: Object to form. 14 THE WITNESS: Yes. 15 BY MR. BUCHANAN: 16 Q. Your obligation in maintaining 17 that closed system is to sell to people who, 18 based on your due diligence and investigation, 19 will likewise maintain that closed system, 19 will likewise maintain that closed system, 19 will likewise maintain that closed system, 19 will place to maintain the closed system, 19 place to maintain the closed system, correct? 20 And to conduct due diligence to 21 assure that their customers have processes in 22 place to maintain the closed system, correct? 23 assure that their customers have processes in 24 place to maintain the closed system, correct? 25 BY MR. BUCHANAN: 26 Q. If he will be a suggestion is 27 to know your customer. The suggestion is 28 to know your customer. The suggestion is 39 to know your customer. The suggestion is 40 a baseling to first, right? 41 A. Yes, to the best of your ability, right? 42 A. Yes, to the best of your ability, right? 43 A. Yes, to the best of your ability, right? 44 A. Yes. 45 BY MR. BUCHANAN: 46 Q. The wind wind wind a suggestion, ma'am. 47 What you took away from that 48 meeting is you must know the customers you're 49 selling to first, right? 40 A. Mm-hmm, yes. 41 A. Yes. 42 Do you see that? 43 A. Disagree. 44 A. Disagree. 45 Do you disagree? 45 A. Disagree. 46 Q. Well, I mean, you'd agree that 47 you disagree? 48 A. I would - 49 MR. BUCHANAN: 40 Devict form. 41 THE WITNESS: - a distributors." 41 A. Disagree. 41 A. Disagree. 42 D. Wald sagree? 43 A. I would - 44 A. Wes. 45 Do you disagree? 45 A. Disagree. 46 Q. Well, I mean, you'd agree that 47 you disagree? 48 A. I would - 49 MR. BUCHANAN: 40 Devict form. 41 Deviction of form. 41 Deviction of form. 41 Deviction of form. 42 Deviction of form. 43 Do you see that? 44 A. Disagree. 45 Deviction of form. 46 Deviction of form. 47 What you took away from that 48 meeting is you must know the customers varied in the condition of the certa	8	what happened. Somebody else will decide	8	MS. VANNI: Object to form.
11 Q. Your obligation is to maintain 12 that closed system, correct? 13 MS. VANNI: Object to form. 14 THE WITNESS: Yes. 15 BY MR. BUCHANAN: 16 Q. Your obligation in maintaining 17 that closed system is to sell to people who, 18 based on your due diligence and investigation, 19 will likewise maintain that closed system, 20 right? 21 A. Yes. 22 Q. And to conduct due diligence to 23 assure that their customers have processes in 24 place to maintain the closed system, correct? 25 assure that their customers have processes in 26 place to maintain the closed system, correct? 27 place to maintain the closed system is 28 to know your customer. The suggestion is 29 to know your customer is customer. 20 g. It is not to know your customer's customer. 20 g. It is not to know your customer's customer. 21 what you took away from that 22 meeting is you must know the customers you're 23 selling to first, right? 24 meeting is you must know the customers you're 25 selling to first, right? 26 Q. And we looked at your document 27 earlier today where you recounted it as you must 28 also know your customers' customers, correct? 39 when you can. 40 Q. The best of your ability, right? 41 A. Yes. 42 Q. Well, I mean, you'd agree that 43 you made 33 billion pills of Vicedin, right? 44 A. Yes, O. Well, you know, all I can do is 45 work with what your former employer gives me, 46 and that's what they've told us it is. 47 Q. What every reasonable 48 Q. What every reasonable 49 manufacturer should do, right? 40 MS. VANNI: Object to form. 41 G. Well, you know, all I can do is 48 work with what your former employer gives me, 49 and that's what they've told us it is. 40 Well, you know, all I can do is 41 work with what your former employer gives me, 41 and that's what they've told us it is. 41 A. Yes. 42 D. Okay. The well are estainly as of 201, right? 43 A. That's what DEA said. 44 Page 331 45 Page 331 46 Page 331 47 Page 331 48 Page 331 49 Page 331 40 Page 331 41 Page 331 42 Page 331 42 Page 331 43 Page 331 44 A. Disagree. 45 Q. W	9	whether it complied or didn't comply.	9	THE WITNESS: Yes.
12 Ms. VANNI: Object to form. 13 Ms. VANNI: Object to form. 14 THE WITNESS: Yes. 15 BY MR. BUCHANAN: 16 Q. Your obligation in maintaining 17 that closed system is to sell to people who, 18 based on your due diligence and investigation, 19 will likewise maintain that closed system, 20 right? 21 A. Yes. 22 Q. And to conduct due diligence to 23 assure that their customers have processes in 24 place to maintain the closed system, correct? 25 assure that their customers have processes in 26 place to maintain the closed system, correct? 27 place to maintain the closed system, correct? 28 place to maintain the closed system, correct? 29 place to maintain the closed system, correct? 20 place to maintain the closed system, correct? 21 place to maintain the closed system, correct? 22 place to maintain the closed system, correct? 23 place to maintain the closed system, correct? 24 place to maintain the closed system, correct? 25 place to maintain the closed system, correct? 26 place to maintain the closed system, correct? 27 place to maintain the closed system, correct? 28 place to maintain the closed system, correct? 29 place to maintain the closed system, correct? 20 place to maintain the closed system, correct? 21 place to maintain the closed system, correct? 22 place to maintain the closed system, correct? 23 place to maintain the closed system, correct? 24 place to maintain the closed system, correct? 25 place to maintain the closed system, correct? 26 place to maintain the closed system, correct? 27 place to maintain the closed system, correct? 28 place to maintain the closed system, correct? 29 place to maintain the closed system, correct? 20 place to maintain the closed system, correct? 21 place to maintain the closed system, correct? 22 place to maintain the closed system, correct? 23 place to maintain the closed system, correct? 24 place to maintain the closed system, correct? 25 place to maintain the closed system, correct? 26 place to maintain the closed system, correct? 27 place to maintain the closed system,	10	A. Yes.	10	BY MR. BUCHANAN:
13	11	Q. Your obligation is to maintain	11	Q. Okay. "People are dying; kids
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18Q. What every reasonable18to exhibit internal number 588. You can19manufacturer should do, right?19set that one aside, ma'am.20MS. VANNI: Objection to form.20(Document marked for21THE WITNESS: If the information21identification as Par-Norton Deposition22is available to you.22Exhibit No. 14.)23BY MR. BUCHANAN:23BY MR. BUCHANAN:				* * *
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22 is available to you. 22 Exhibit No. 14.) 23 BY MR. BUCHANAN: 23 BY MR. BUCHANAN:		· · · · · · · · · · · · · · · · · · ·		`
23 BY MR. BUCHANAN: 23 BY MR. BUCHANAN:				
		· · · · · · · · · · · · · · · · · · ·		
	24	Q. Right. And, certainly, if	24	Q. Passing you next in order is
Q. 1 400 mg you new m vider to				

```
Page 334
                                                                                                         Page 336
                                                               1
 1
        Exhibit Number 14. There you go. Copy for
                                                                              And so we know, ma'am, that you
 2
                                                               2
        counsel, please.
                                                                     had received a letter by 2007 -- and I guess you
                                                               3
 3
                 Next in order, ma'am, is a SOMS
                                                                     weren't at Qualitest then, but you were at
 4
                                                               4
                                                                     Watson or Anda, where manufacturers and
        update. Do you see you scheduling a conference
 5
        call to update folks?
                                                               5
                                                                     distributors received a letter concerning
                                                               6
 6
                                                                     maintenance of effective controls against
             A.
                  Yes.
 7
                  We don't have the --
                                                               7
                                                                     diversion.
             Q.
 8
             A.
                 Not sure who, yeah.
                                                               8
                                                                              Do you recall that?
                                                               9
 9
            Q. I was just going to say, we don't
                                                                          A. Yes.
10
        know who the invitees are. This is just the way
                                                             10
                                                                              MS. KOSKI: Object to form.
11
        we get them. They're already printed out and
                                                             11
                                                                              MS. LEIBELL: Object to form.
                                                             12
12
        stamped when we get them, for the most part.
                                                                     BY MR. BUCHANAN:
13
        Some of these come to us natively, but you will
                                                             13
                                                                          Q. And the obligation -- the
                                                             14
14
        see that on the next page.
                                                                     obligation that manufacturers and distributors
15
                                                             15
                                                                     had to maintain effective controls against
                 This is from November of 2013.
                                                             16
16
                 MR. BUCHANAN: What did we call
                                                                     diversion, right?
17
                                                             17
                                                                          A. Yes.
             this, 14? Exhibit 14. Can we put it up
18
                                                             18
                                                                          Q. Okay. And what this is saying as
            on the screen? Bradley, let's go to the
19
            third -- fourth page.
                                                             19
                                                                     of the fall of 2013 is that Phase I of this
20
                                                             20
        BY MR. BUCHANAN:
                                                                     revamp is to implement a basic SOMS program for
                                                             21
21
            Q. "SOMS Program Update, November 7,
                                                                     all of your customers, right; that's one part,
        2013." This is a presentation you pulled
22
                                                             22
                                                                     correct?
23
        together for a teleconference or a meeting?
                                                             23
                                                                              MS. VANNI: Object to form.
24
                                                             24
                                                                              THE WITNESS: That's what it
                 Yes, looks that way.
                                           Page 335
                                                                                                         Page 337
 1
                  Okay. And you broke down what
                                                               1
                                                                          savs.
 2
        was happening with regard to the SOMS program
                                                               2
                                                                     BY MR. BUCHANAN:
 3
        into multiple phases, right?
                                                               3
                                                                                For all controlled substances,
                                                                          O.
 4
                                                               4
            A.
                  Yes.
                                                                     correct?
 5
                  You had steps that you were going
                                                               5
                                                                                That's what it says, yes.
                                                                          A.
 6
        to implement as you tried to revamp things,
                                                               6
                                                                          O.
                                                                                With a statistical algorithm?
 7
                                                               7
        right?
                                                                          A.
                                                                                Yes, that's correct.
 8
                 MS. VANNI: Object to form.
                                                               8
                                                                                Okay. And so one of the things
 9
                 THE WITNESS: Yes.
                                                               9
                                                                     you were doing then to implement this for all
10
                                                             10
        BY MR. BUCHANAN:
                                                                     classes of trade and all customers and for all
11
                                                             11
            Q. Okay. Phase I, your first step
                                                                     controlled substances in the fall of 2013 is you
12
        was to implement a basic SOMS program, right?
                                                             12
                                                                     hired this company, Cegedim -- am I pronouncing
13
                                                             13
             A. No. The first step was to
                                                                     that right?
14
        implement the basic SOMS program with
                                                             14
                                                                          A.
                                                                                Yes.
15
        statistical algorithm, that's the rest of the
                                                             15
                                                                                Is it Cegedim?
                                                                          O.
16
                                                             16
        sentence there.
                                                                                Cegedim.
17
                  Well, actually, it's not. If you
                                                             17
                                                                                Cegedim, okay. You hired Cegedim
18
        want to read the full sentence, I'm happy to.
                                                             18
                                                                     to help you put together an algorithm that would
19
                 It's "Implementation of a basic
                                                             19
                                                                     do what's reflected here, right?
20
        SOMS program for all customers," right?
                                                             20
                                                                          A.
21
                                                             21
                                                                                And to implement it not just for
                  All controlled substances and
22
        pseudoephedrine products based on statistical
                                                             22
                                                                     some customers, but to implement it for all
23
        algorithm.
                                                             23
                                                                     classes of trade and all customers, right?
24
                                                             24
                Right.
                                                                               MS. VANNI: Object to form.
            Q.
```

Page 338 Page 340 THE WITNESS: Basically to 1 Was there a manager of the SOM 1 2 program in title, prior to that point in time? 2 automate the program, yes. 3 BY MR. BUCHANAN: 3 A. Not that title, no. Q. Phase II is to "Hire individuals 4 Q. Right. 4 5 to support the program," right? 5 There was no manager of the SOM 6 Yes. 6 program in Qualitest prior to September of A. 2014 -- 2013, excuse me? 7 Q. Okay. Well, let's go back, I'm 7 8 sorry, to Phase I. You said to automate the 8 A. Yes, that's correct. Doesn't 9 9 mean it wasn't being done. Q. All right. So -- and someone 10 We've looked at documents today, 10 11 you agree we've looked at documents where the 11 else is going to decide that, ma'am, so let's -can we agree there was nobody at Qualitest who 12 company is saying it was only looking at retail 12 pharmacies as a class of trade. had that title prior to September of 2013? 13 13 A. Not that title, correct. Do you recall looking at those 14 14 15 documents, ma'am, yes or no? 15 Q. Okay. And what you noted here is A. Yes, we were only looking at you're going to hire individuals to support the 16 16 17 retail customers for the SOMS program, not the 17 program, right? 18 OMS program. 18 Yes. A. 19 Thank you. 19 One of the things you did was you O. 20 "Phase II, Hire individuals to 20 hired somebody as director of SOMS, support the program," right? 588.6, that's on Mr. Brantley? 21 21 the screen to your -- we put one to your left 22 22 A. Manager of SOMS, yes. 23 too. That may not be the most optimal location. 23 There you go. A. Yes, I see it. This is good. "All individuals on board and 24 24 Page 339 Page 341 actively working on other aspects of the 1 Q. Okay. So, certainly, if you're 1 2 program," right? 2 going to have an effective program, you've got 3 to have people as part of this process, right? 3 A. Yes. MS. VANNI: Object to form. 4 One of things you needed was 4 THE WITNESS: We had people as 5 personnel training, right? 5 6 part of the process. They were just in 6 A. Yes. 7 7 sales and the perception was not good, Q. You had to implement SOPs, right? 8 so we moved them into compliance. Yes. A. 9 9 BY MR. BUCHANAN: You had to develop O. 10 10 questionnaires, distribute questionnaires, get Right. 11 responses from questionnaires for their customer 11 And you're going to have to put 12 boots on the ground too and do due diligence 12 SOMS data, right? 13 13 visits and do all kinds of stuff, right? A. Yes. 14 MS. VANNI: Object to form. 14 Okay. You had to create customer THE WITNESS: So that sales 15 15 boundaries, that was one of the things you were 16 16 doesn't have to do it, yes. going to do, right? 17 17 MS. VANNI: Object to form. BY MR. BUCHANAN: 18 Q. Well, one of things we know you 18 THE WITNESS: That was using the 19 did is you brought in Mr. Brantley, right? 19 IMS data. A. Yes, I did. 20 BY MR. BUCHANAN: 20 21 Q. I mean, you needed -- I mean, 21 Q. Okay. So to create as part of 22 22 this individual customer boundary so that you'd what was his title? 23 have flags as to unusual order sizes when they 23 A. He was a manager of the SOM 24 24 went beyond boundaries for various classes of program.

	Page 342		Page 344
1	trade, right?	1	Q. All right. And we've talked
2	MS. VANNI: Object to form.	2	about what the old program was, and this talked
3	THE WITNESS: Yes, for the	3	about what it covered, and now we're talking
4	automated system, yes.	4	about your various phases for revamping it,
5	BY MR, BUCHANAN:	5	right?
6	Q. And the next thing here that you	6	A. Yes, the enhancements to the
7	were going to implement is due diligence visits,	7	existing program.
8	right?	8	Q. Okay. Next, Phase IV, boots on
9	A. Yes, by someone with compliance.	9	the ground, right?
10	Q. And it sounds, ma'am, like what's	10	A. Yes.
11	happening is withdrawn.	11	Q. Okay. "Customer Due Diligence
12	Phase III, next page. 588.7.	12	Visits," right, know your customer?
13	A. Yes.	13	A. Yes, correct.
14	Q. "Develop capability to easily	14	Q. Okay. Because there were some
15	access, trend and sort chargeback data,"	15	direct customers that were in the DEA binder,
16	correct?	16	you know, some big distributors, right?
17	A. Yes.	17	A. Yes.
18	Q. You worked with the vendor from	18	Q. There were six, I think, charts
19	IQ2020, or you worked with a vendor called	19	that reflected McKesson. There were five that
20	IQ2020.	20	reflected CVS. There were two that reflected HD
21	Do you recall that?	21	Smith, right?
22	A. We gave a demo. I had seen a	22	A. Our intent was to target the
23	demo from them previously, and we shared that	23	customers that were identified in there first,
24	demo with the finance folks.	24	yes.
	Page 343		Page 345
1		1	_
1 2	Q. Okay. And so a demo was given to	1 2	
			Q. Right. And these have been
2	Q. Okay. And so a demo was given to the finance folks. You said an agreement was	2	Q. Right. And these have been called out in the DEA binder as, hey, these are
2 3	Q. Okay. And so a demo was given to the finance folks. You said an agreement was reached with them, right?	2 3	Q. Right. And these have been called out in the DEA binder as, hey, these are people that you're buying they're well above the
2 3 4	Q. Okay. And so a demo was given to the finance folks. You said an agreement was reached with them, right? A. Yes.	2 3 4	Q. Right. And these have been called out in the DEA binder as, hey, these are people that you're buying they're well above the norms, right?
2 3 4 5	Q. Okay. And so a demo was given to the finance folks. You said an agreement was reached with them, right? A. Yes. Q. IT resources were implemented to	2 3 4 5	Q. Right. And these have been called out in the DEA binder as, hey, these are people that you're buying they're well above the norms, right? MS. VANNI: Object to form.
2 3 4 5 6	Q. Okay. And so a demo was given to the finance folks. You said an agreement was reached with them, right? A. Yes. Q. IT resources were implemented to capture the feed, right?	2 3 4 5 6	Q. Right. And these have been called out in the DEA binder as, hey, these are people that you're buying they're well above the norms, right? MS. VANNI: Object to form. THE WITNESS: They had large
2 3 4 5 6 7	Q. Okay. And so a demo was given to the finance folks. You said an agreement was reached with them, right? A. Yes. Q. IT resources were implemented to capture the feed, right? MS. VANNI: Object to form.	2 3 4 5 6 7	Q. Right. And these have been called out in the DEA binder as, hey, these are people that you're buying they're well above the norms, right? MS. VANNI: Object to form. THE WITNESS: They had large quantities that needed to be researched
2 3 4 5 6 7 8	Q. Okay. And so a demo was given to the finance folks. You said an agreement was reached with them, right? A. Yes. Q. IT resources were implemented to capture the feed, right? MS. VANNI: Object to form. THE WITNESS: Yes.	2 3 4 5 6 7 8	Q. Right. And these have been called out in the DEA binder as, hey, these are people that you're buying they're well above the norms, right? MS. VANNI: Object to form. THE WITNESS: They had large quantities that needed to be researched or DEA thought they were large
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2 3 4 5 6 7 8 9	Q. Okay. And so a demo was given to the finance folks. You said an agreement was reached with them, right? A. Yes. Q. IT resources were implemented to capture the feed, right? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. And then you're going to plan to further develop this with leadership, I guess that's Mike and Trey?	2 3 4 5 6 7 8 9	Q. Right. And these have been called out in the DEA binder as, hey, these are people that you're buying they're well above the norms, right? MS. VANNI: Object to form. THE WITNESS: They had large quantities that needed to be researched or DEA thought they were large quantities, yes. BY MR. BUCHANAN: Q. Right. So you were going to put boots on the ground first to customers that had
2 3 4 5 6 7 8 9 10	Q. Okay. And so a demo was given to the finance folks. You said an agreement was reached with them, right? A. Yes. Q. IT resources were implemented to capture the feed, right? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. And then you're going to plan to further develop this with leadership, I guess	2 3 4 5 6 7 8 9 10	Q. Right. And these have been called out in the DEA binder as, hey, these are people that you're buying they're well above the norms, right? MS. VANNI: Object to form. THE WITNESS: They had large quantities that needed to be researched or DEA thought they were large quantities, yes. BY MR. BUCHANAN: Q. Right. So you were going to put boots on the ground first to customers that had been flagged, right?
2 3 4 5 6 7 8 9 10 11 12	Q. Okay. And so a demo was given to the finance folks. You said an agreement was reached with them, right? A. Yes. Q. IT resources were implemented to capture the feed, right? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. And then you're going to plan to further develop this with leadership, I guess that's Mike and Trey?	2 3 4 5 6 7 8 9 10 11 12	Q. Right. And these have been called out in the DEA binder as, hey, these are people that you're buying they're well above the norms, right? MS. VANNI: Object to form. THE WITNESS: They had large quantities that needed to be researched or DEA thought they were large quantities, yes. BY MR. BUCHANAN: Q. Right. So you were going to put boots on the ground first to customers that had
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. Okay. And so a demo was given to the finance folks. You said an agreement was reached with them, right? A. Yes. Q. IT resources were implemented to capture the feed, right? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. And then you're going to plan to further develop this with leadership, I guess that's Mike and Trey? A. That's the sales team. Q. Got you. That was Phase III, right, and that's chargeback data? A. Yes. Q. That was another new addition to	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. Right. And these have been called out in the DEA binder as, hey, these are people that you're buying they're well above the norms, right? MS. VANNI: Object to form. THE WITNESS: They had large quantities that needed to be researched or DEA thought they were large quantities, yes. BY MR. BUCHANAN: Q. Right. So you were going to put boots on the ground first to customers that had been flagged, right? MS. VANNI: Object to form. BY MR. BUCHANAN: Q. In that DEA presentation, right? A. Yes. Q. But you also sent out a dear
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. Okay. And so a demo was given to the finance folks. You said an agreement was reached with them, right? A. Yes. Q. IT resources were implemented to capture the feed, right? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. And then you're going to plan to further develop this with leadership, I guess that's Mike and Trey? A. That's the sales team. Q. Got you. That was Phase III, right, and that's chargeback data? A. Yes. Q. That was another new addition to the program, right?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. Right. And these have been called out in the DEA binder as, hey, these are people that you're buying they're well above the norms, right? MS. VANNI: Object to form. THE WITNESS: They had large quantities that needed to be researched or DEA thought they were large quantities, yes. BY MR. BUCHANAN: Q. Right. So you were going to put boots on the ground first to customers that had been flagged, right? MS. VANNI: Object to form. BY MR. BUCHANAN: Q. In that DEA presentation, right? A. Yes. Q. But you also sent out a dear valued customer to every customer, correct?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Okay. And so a demo was given to the finance folks. You said an agreement was reached with them, right? A. Yes. Q. IT resources were implemented to capture the feed, right? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. And then you're going to plan to further develop this with leadership, I guess that's Mike and Trey? A. That's the sales team. Q. Got you. That was Phase III, right, and that's chargeback data? A. Yes. Q. That was another new addition to the program, right? MS. VANNI: Object to form. THE WITNESS: That was one new addition to the program, one improvement	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Right. And these have been called out in the DEA binder as, hey, these are people that you're buying they're well above the norms, right? MS. VANNI: Object to form. THE WITNESS: They had large quantities that needed to be researched or DEA thought they were large quantities, yes. BY MR. BUCHANAN: Q. Right. So you were going to put boots on the ground first to customers that had been flagged, right? MS. VANNI: Object to form. BY MR. BUCHANAN: Q. In that DEA presentation, right? A. Yes. Q. But you also sent out a dear valued customer to every customer, correct? A. Correct. Q. That was the October 18 letter that we looked at earlier today, correct?

nk you. A. Yes. Q. And you sent a notice to your ect customers that there were customers of ir customers customers of that customer that been flagged as part of that DEA esentation, correct? A. Yes. Q. Okay. A. We couldn't contact them ectly, so we went through the direct etomer. Q. Okay. "SOMS Brand Business alysis," is it correct, ma'am, that you did thave responsibility in your DEA compliance	1 2 3 4 5 6 7 8 9 10 11 12	THE WITNESS: Yes, I believe so. MR. BUCHANAN: Okay. Could we pull it up on the screen. BY MR. BUCHANAN: Q. This is an e-mail from yourself to Ms. Connell. She was was she your boss? A. She was my boss at the time. Q. Okay. "Subject: DEA Compliance Initiatives Presentation," and there's a PowerPoint that's attached entitled "DEA
A. Yes. Q. And you sent a notice to your ect customers that there were customers of ir customers customers of that customer thad been flagged as part of that DEA esentation, correct? A. Yes. Q. Okay. A. We couldn't contact them ectly, so we went through the direct estomer. Q. Okay. "SOMS Brand Business alysis," is it correct, ma'am, that you did	3 4 5 6 7 8 9 10 11 12	pull it up on the screen. BY MR. BUCHANAN: Q. This is an e-mail from yourself to Ms. Connell. She was was she your boss? A. She was my boss at the time. Q. Okay. "Subject: DEA Compliance Initiatives Presentation," and there's a PowerPoint that's attached entitled "DEA
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stomer. Q. Okay. "SOMS Brand Business alysis," is it correct, ma'am, that you did	12	
stomer. Q. Okay. "SOMS Brand Business alysis," is it correct, ma'am, that you did		Compliance Initiative" from February 9, 2013.
alysis," is it correct, ma'am, that you did		Do you see that, ma'am?
alysis," is it correct, ma'am, that you did	13	A. Yes.
	14	Q. Okay. At 1052.3 there's a
	15	summary of this particular meeting with Buzzeo
e for what was happening on the branded side,	16	PDMA.
I we'll just call that Endo?	17	Do you see that at the top?
A. Yes, that's correct.	18	A. Yes.
Q. Okay. Now, before the DEA told	19	Q. "On January 16th and 17th, 2013,
that your current SOMS system was	20	a review of our Suspicious Order Monitoring
dequate, you had been told that by other	21	System was conducted by external consultants
ople, right?	22	working for Buzzeo PDMA."
MS. VANNI: Object to form.	23	Do you see that?
THE WITNESS: DEA actually didn't	24	A. Yes, I do.
·		
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tell us it was inadequate.	1	Q. Okay. The paragraph in the
MR. BUCHANAN:	2	middle begins, "The consultants concluded."
Q. Well, we have the we have the	3	Do you see that?
cussion	4	A. I do.
A. We have the discuss	5	Q. Can you read that into the
Q and the jury can characterize	6	record, ma'am?
se findings, and we have your words on it as	7	A. "The consultants concluded that
ll from that time, but let's before that	8	our current SOM program, systems and procedures
eting in March, you had had interactions with	9	do not meet the regulatory requirements."
company with consultants concerning your	10	Q. Let's pause there.
MS system, correct?	11	A. Mm-hmm.
A. I don't recall who.	12	Q. This is of course, just to
Q. Okay. Let's start with	13	orient ourselves in time, this is two months
MR. BUCHANAN: Can I have 1052.	14	prior to sitting down with the DEA, correct?
(Document marked for	15	A. Correct.
	16	Q. And what your consultants told
identification as Par-Norton Deposition	17	you as of this point in time and before the time
identification as Par-Norton Deposition	18	with the DEA is that your current SOM program,
`	19	systems and procedures do not even meet the
identification as Par-Norton Deposition Exhibit No. 15.) MR. BUCHANAN:	20	regulatory requirements, right?
identification as Par-Norton Deposition Exhibit No. 15.) YMR. BUCHANAN: Q. Passing you, ma'am, what we're a		MS. VANNI: Object to form.
identification as Par-Norton Deposition Exhibit No. 15.) MR. BUCHANAN: Q. Passing you, ma'am, what we're a rking as Exhibit 15 to your deposition.	21	•
identification as Par-Norton Deposition Exhibit No. 15.) MR. BUCHANAN: Q. Passing you, ma'am, what we're a rking as Exhibit 15 to your deposition. You had some of these folks from	21 22	THE WITNESS: Right because it
identification as Par-Norton Deposition Exhibit No. 15.) MR. BUCHANAN: Q. Passing you, ma'am, what we're a rking as Exhibit 15 to your deposition.	21 22 23	THE WITNESS: Right, because if they met the regulatory requirements,
	Exhibit No. 15.) MR. BUCHANAN: Q. Passing you, ma'am, what we're a	Exhibit No. 15.) 17 MR. BUCHANAN: 18 Q. Passing you, ma'am, what we're a 19 ting as Exhibit 15 to your deposition. 20 You had some of these folks from 21

Page 352 Page 350 1 1 sums to implement a new program. Yes. BY MR. BUCHANAN: 2 2 O. Okay. And so the consultants 3 Q. Well, certainly, ma'am, before 3 concluded that your current systems, procedures somebody had to sit in this chair and talk about 4 and program for SOM did not meet the regulatory 4 5 5 requirements, and then they made specific this document --6 Whether somebody sat in this recommendations, correct? 6 A. 7 7 A. Yes, that's what it says. chair or not. 8 8 Q. Well, you certainly didn't write Q. Okay. And one of the 9 9 recommendations they made was increase the that, right? 10 MS. VANNI: Object to form. 10 amount of initial due diligence to include on 11 THE WITNESS: We wrote what this 11 site meetings with customers to assure they have 12 12 controls in place to safeguard against is. It's minutes. 13 13 BY MR. BUCHANAN: diversion. Q. I invite you to review this and 14 14 Do you see that? 15 say -- and see if at any point in time you wrote 15 Yes. A. here, we have to take this all with a grain of 16 16 Q. Okay. That's what the DEA talked 17 salt because they're just trying to make money? 17 to you about two months later, right? 18 MS. VANNI: Object to form. 18 MS. VANNI: Object to form. 19 BY MR. BUCHANAN: 19 THE WITNESS: Yes. 20 20 Q. In words or substance? BY MR. BUCHANAN: 21 A. I actually didn't write this. 21 Q. Okay. Let's go to item 2, 22 Q. Okay. Can we see in there 22 "Remove the Sales & Marketing and Customer 23 anywhere where the author of this characterized 23 Service functions from the SOM decision-making in words or substance they're just trying to 24 24 process as conducting this review is contrary to Page 351 Page 353 1 make money off us? 1 their primary mission of helping accounts with 2 their current business and encouraging new 2 MS. VANNI: Object to the form. 3 THE WITNESS: They wouldn't put 3 business," right? that in here because they're trying --4 That's what the minutes say, yes. 5 we're trying to bring this company on to 5 Right. And, in fact, I mean, you 6 make improvements to the system. 6 heard the same thing from the DEA in March, 7 7 right, that you got to take customer service and BY MR. BUCHANAN: 8 8 sales out of the site inspection and out of that Q. Right. 9 9 So what they wrote is the process, correct? 10 10 consultants concluded that our current -- and A. Yes. 11 11 they spent two days with you, right? MS. VANNI: Object to form. 12 A. I'm not sure. It says, "Tracey 12 THE WITNESS: The perception is 13 13 was not able to participate due to an there. 14 unannounced DEA inspection." 14 BY MR. BUCHANAN: 15 15 Q. Right. Q. Well, in fact, these consultants, 16 not just the DEA, these consultants who you 16 So we have Aimee Cooper, Bambi 17 McGaha, Ricky Richardson, Larry Shaffer and 17 called in to do an inspection of your system, 18 Jeremy Tatum, correct? 18 told you that you got to get customer service 19 19 Yes and sales and marketing out of the SOM process, Α 20 Q. And we talked about Mr. -- I 20 right? 21 21 MS. VANNI: Object to form. pronounced it Shaffer again. 22 A. Shaffer. 22 THE WITNESS: Yes, they had that 23 23 Mr. Shaffer was in your perception too. O. 24 BY MR. BUCHANAN: 24 organization?

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1 Q. Okay. They raised a concern	1	A. That's correct.
2 about your "Retail thresholds appear to be based	2	Q. Do you agree that
3 upon perceived abuse potential and might be	3	A. That's common sense.
4 characterized as arbitrary."	4	Q. Yeah, I mean, because if you
5 Do you see that?	5	share with customers what the thresholds are
6 A. Yes.	6	that you've set, they can structure their orders
7 Q. And one of the things you did	7	in a way so that they stay below the thresholds
8 after the DEA presentation in March of 2013 was	8	all the time but get to the same place in a
9 develop a different algorithm to develop your	9	different way?
10 thresholds, correct?	10	A. Right, which is why we didn't
MS. VANNI: Object to form.	11	share those.
12 THE WITNESS: We developed an	12	Q. Right. So sharing thresholds,
algorithm to build pattern and frequency	13	bad practice, right?
14 into the initial check.	14	A. Yes.
15 BY MR. BUCHANAN:	15	Q. Okay. Working with orders to
16 Q. Okay. So that your system, the	16	working with customers to structure their orders
system for suspicious order monitoring, I'm up	17	so they stay within thresholds is not a good
to 5 on the next page, just trying to move	18	practice?
19 quickly, ma'am, "System should be tested,	19	A. No, it's not.
validated and statistically defensible."	20	MS. VANNI: Object to form.
21 Do you see that?	21	BY MR. BUCHANAN:
22 A. Yes.	22	Q. I mean, the manufacturer or the
Q. Do you agree with that?	23	distributor should not be working with its
24 A. Yes, that's their standard	24	primary customer to structure its order in a way
,		
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wording for that particular vendor, that's their	1	to stay within whatever the red flag thresholds
2 standard wording, yes.	2	are, right?
Q. But do you agree, I mean, if	3	MS. VANNI: Object to form.
4 you're going to have a system for detecting	4	THE WITNESS: No, that defeats
5 suspicious orders, that it should be tested,	5	the purpose of the program.
6 validated and defensible?	6	BY MR. BUCHANAN:
7 A. Any computer system should be	7	Q. Right.
8 validated. It's an FDA requirement, yes.	8	That's a very bad practice,
9 Q. Well, I'm not talking about FDA	9	right?
10 requirements, ma'am.	10	A. Yes.
I just want to know do you agree	11	Q. And if you're doing that kind of
with regard to suspicious order monitoring, the	12	practice and you're certainly not maintaining
system should be tested, validated and	13	effective controls against diversion, right?
14 defensible?	14	MS. VANNI: Object to form.
15 A. Yes.	15	THE WITNESS: That's correct.
16 Q. Okay, good. Statistically	16	However, customers can, over time, if
defensible, you agree?	17	they're a regular customer, kind of
18 A. Yes.	18	figure out what your threshold is. You
19 Q. Okay. And they advised further	19	don't communicate it to them, but if
20 that you should not provide customers for the	20	they're smart and they keep track of it,
reason their orders are held or pended as this	21	they can technically figure it out.
may result in customers working to avoid the one	22	BY MR. BUCHANAN:
item that caused the order to be declined.	23	Q. But as a manufacturer, you need
Do you see that?	24	to be vigilant to make sure your customers are

	Page 358		Page 360
1	not structuring transactions to evade	1	the consultant said.
2	A. Absolutely, yes.	2	BY MR. BUCHANAN:
3	Q these type of limits, correct?	3	Q. Right. And so you certainly in
4	MS. VANNI: Object to form.	4	passing along the information you received from
5	THE WITNESS: Yes.	5	the consultant, forwarded along their top level
6	BY MR. BUCHANAN:	6	conclusion, right?
7	Q. And then you go through to	7	MS. VANNI: Object to form.
8	summarize in your PowerPoint, ma'am, and this is	8	THE WITNESS: I was not at the
9	a PowerPoint that you obviously endorsed, right?	9	meeting with the consultant, so I was
10	MS. VANNI: Object to the form.	10	just going by what the individual told
11	THE WITNESS: I don't know if I	11	me was said at the meeting and just
12	created it.	12	communicating that information.
13	BY MR. BUCHANAN:	13	BY MR. BUCHANAN:
14	Q. Well, if we go back to 1052.1.	14	Q. And for the benefit of your
15	This is a PowerPoint you forwarded to your boss,	15	boss
16	right?	16	A. It does not
17	A. Yes.	17	Q in passing this along, top
18	Q. Okay. Ms. Connell was your boss	18	level conclusion that you passed along, "The
19	at that point in time?	19	consultants concluded that our current SOM
20	A. Correct.	20	program, systems and procedures do not meet the
21	Q. So, obviously, if you forwarded	21	regulatory requirements," correct?
22	this, you, obviously, endorsed its content,	22	A. That's what it says, yes.
23	right?	23	Q. And that was point one
24	A. Yes.	24	substantively that you conveyed to your boss,
	Page 359		Page 361
1	MC VANNIL Object to the forms		
1 1	MS VANINE Object to the form	1	right?
2	MS. VANNI: Object to the form. BY MR. BUCHANAN:	1 2	right? MS. VANNI: Object to form.
	BY MR. BUCHANAN:	2	MS. VANNI: Object to form.
2	BY MR. BUCHANAN: Q. And you forwarded along the		MS. VANNI: Object to form. THE WITNESS: That doesn't mean I
2	BY MR. BUCHANAN: Q. And you forwarded along the Cegedim report and conclusions and	2 3	MS. VANNI: Object to form.
2 3 4	BY MR. BUCHANAN: Q. And you forwarded along the Cegedim report and conclusions and recommendations, right?	2 3 4	MS. VANNI: Object to form. THE WITNESS: That doesn't mean I agreed with it, but yes. BY MR. BUCHANAN:
2 3 4 5	BY MR. BUCHANAN: Q. And you forwarded along the Cegedim report and conclusions and recommendations, right? A. Yes, looks like I did.	2 3 4 5	MS. VANNI: Object to form. THE WITNESS: That doesn't mean I agreed with it, but yes. BY MR. BUCHANAN: Q. Okay. Well, you certainly didn't
2 3 4 5 6 7	BY MR. BUCHANAN: Q. And you forwarded along the Cegedim report and conclusions and recommendations, right? A. Yes, looks like I did. Q. And so the PowerPoint begins on	2 3 4 5 6 7	MS. VANNI: Object to form. THE WITNESS: That doesn't mean I agreed with it, but yes. BY MR. BUCHANAN: Q. Okay. Well, you certainly didn't put any qualifiers in what you sent to her,
2 3 4 5 6	BY MR. BUCHANAN: Q. And you forwarded along the Cegedim report and conclusions and recommendations, right? A. Yes, looks like I did. Q. And so the PowerPoint begins on I'm sorry, 1052.7.	2 3 4 5 6	MS. VANNI: Object to form. THE WITNESS: That doesn't mean I agreed with it, but yes. BY MR. BUCHANAN: Q. Okay. Well, you certainly didn't put any qualifiers in what you sent to her, right?
2 3 4 5 6 7 8	BY MR. BUCHANAN: Q. And you forwarded along the Cegedim report and conclusions and recommendations, right? A. Yes, looks like I did. Q. And so the PowerPoint begins on	2 3 4 5 6 7 8	MS. VANNI: Object to form. THE WITNESS: That doesn't mean I agreed with it, but yes. BY MR. BUCHANAN: Q. Okay. Well, you certainly didn't put any qualifiers in what you sent to her,
2 3 4 5 6 7 8 9	BY MR. BUCHANAN: Q. And you forwarded along the Cegedim report and conclusions and recommendations, right? A. Yes, looks like I did. Q. And so the PowerPoint begins on I'm sorry, 1052.7. MR. BUCHANAN: If you can go	2 3 4 5 6 7 8	MS. VANNI: Object to form. THE WITNESS: That doesn't mean I agreed with it, but yes. BY MR. BUCHANAN: Q. Okay. Well, you certainly didn't put any qualifiers in what you sent to her, right? MS. VANNI: Object to form.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY MR. BUCHANAN: Q. And you forwarded along the Cegedim report and conclusions and recommendations, right? A. Yes, looks like I did. Q. And so the PowerPoint begins on I'm sorry, 1052.7. MR. BUCHANAN: If you can go there, please, Bradley, for everyone's benefit. BY MR. BUCHANAN: Q. And you've got your agenda on the next page and an overview of the Cegedim report, right? A. Yes. Q. And then you've got the first bullet on page 1052.10. A. Yes. Q. Called out for your boss, right?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MS. VANNI: Object to form. THE WITNESS: That doesn't mean I agreed with it, but yes. BY MR. BUCHANAN: Q. Okay. Well, you certainly didn't put any qualifiers in what you sent to her, right? MS. VANNI: Object to form. THE WITNESS: I wouldn't have put it in writing if I'm giving her what they said. We would have had a side conversation. BY MR. BUCHANAN: Q. Okay. Specifically, they recommended we make the following changes, increase the amount of initial due diligence with customers, right? A. Yes. Q. To assure our customers have

	Page 362		Page 364
1	customers have their own robust SOMS program,	1	meeting.
2	right?	2	Q. Okay. "Remove the Sales &
3	A. Yes.	3	Marketing and Customer Service functions from
4	Q. So it's being recommended and	4	the SOM decision-making process," right?
5	what you're communicating to your boss is having	5	A. Yes.
6	due diligence that's going to confirm that your	6	Q. Okay. And you note, "The DEA
7	customers have robust SOMS programs, right?	7	Compliance Department is best suited for this
8	MS. VANNI: Object to form.	8	purpose as DEA compliance personnel have a
9	THE WITNESS: There's are all the	9	singular mission of protecting the firm from
10	recommendations of the Cegedim report,	10	regulatory issues and should be assigned the
11	yes.	11	primary role of conducting due diligence,
12	BY MR. BUCHANAN:	12	evaluating pended or possibly suspicious orders,
13	Q. Right. And this is months before	13	and clearing accounts or reporting the records
14	the DEA meeting, right?	14	to DEA."
15	A. Yes.	15	Did I read that correctly?
16	Q. Okay. Review their SOPs and	16	MS. VANNI: Object to form.
17	orders themselves, correct?	17	THE WITNESS: Quoted, yep, word
18	A. Yes.	18	for word
19	Q. I mean, let me restate that.	19	BY MR. BUCHANAN:
20	"Increase the amount of initial	20	Q. Makes perfect sense.
21	due diligence with customers to assure our	21	A by the consultant, yes.
22	customers have their own robust SOMS program,"	22	MS. VANNI: Object to form.
23	correct?	23	BY MR. BUCHANAN:
24	A. Yes, that's what it says.	24	Q. Makes perfect sense?
2 1	A. 1 cs, mars what it says.	21	Q. Wakes perfect sense:
	Page 363		Page 365
1	Q. That's what you wrote.	1	A. These are their opinions, yes.
2	· · · · · · · · · · · · · · · · · · ·		
	"(Review of their SOPs and orders	2	Q. Okay. Well, I mean, look you
3	· · · · · · · · · · · · · · · · · · ·	2 3	Q. Okay. Well, I mean, look you
3 4	they themselves have reported to DEA)," correct? A. Yes.		Q. Okay. Well, I mean, look you pay you brought them in, right?
	they themselves have reported to DEA)," correct? A. Yes.	3	Q. Okay. Well, I mean, look you pay you brought them in, right? A. Yes, they have
4	they themselves have reported to DEA)," correct? A. Yes. Q. "Our process should include	3 4	Q. Okay. Well, I mean, look you pay you brought them in, right? A. Yes, they have Q. You brought them in for the
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4 5 6	they themselves have reported to DEA)," correct? A. Yes. Q. "Our process should include on-site meetings (audits) for both Corporate Offices and Distribution Centers," right?	3 4 5 6 7	Q. Okay. Well, I mean, look you pay you brought them in, right? A. Yes, they have Q. You brought them in for the experience they could bring to the evaluation to evaluate your system and give you
4 5 6 7	they themselves have reported to DEA)," correct? A. Yes. Q. "Our process should include on-site meetings (audits) for both Corporate Offices and Distribution Centers," right? A. That's what they said, yes.	3 4 5 6	Q. Okay. Well, I mean, look you pay you brought them in, right? A. Yes, they have Q. You brought them in for the experience they could bring to the evaluation to evaluate your system and give you recommendations, right?
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	they themselves have reported to DEA)," correct? A. Yes. Q. "Our process should include on-site meetings (audits) for both Corporate Offices and Distribution Centers," right? A. That's what they said, yes. Q. And that's what you communicated to your boss, right? MS. VANNI: Object to form. THE WITNESS: Word for word what the consultant reported. BY MR. BUCHANAN: Q. That's not quite word for word, but you've recast it and put it in this form A. Yes. Q for your boss, right? MS. VANNI: Object to form. BY MR. BUCHANAN: Q. This is how you understood their	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Okay. Well, I mean, look you pay you brought them in, right? A. Yes, they have Q. You brought them in for the experience they could bring to the evaluation to evaluate your system and give you recommendations, right? A. I brought them in for their electronic monitoring system, which was the best in the industry at the time. Q. You brought them in to conduct an audit of your suspicious order monitoring system, correct? MS. VANNI: Object to form. THE WITNESS: I didn't need them to conduct an audit. I'm capable of conducting an audit myself. BY MR. BUCHANAN: Q. Okay. So you're saying this was all known to you then as of this point in time,
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	Page 366		Page 368
1	BY MR. BUCHANAN:	1	you that, that was, in fact, the consultants you
2	Q. You were aware of all these	2	hired and paid good money to come in and assess
3	points?	3	your system?
4	A. I did not agree with their	4	MS. VANNI: Object to form.
5	recommendations. I knew the condition of our	5	THE WITNESS: The consultants
6	current SOM program, and I knew I wanted to make	6	that got it from DEA, yes.
7	improvements.	7	BY MR. BUCHANAN:
8	Q. The further recommendation is	8	Q. Okay. The "System should be
9	"Discontinue the use of thresholds and forecasts	9	tested validated and statistically defensible,"
10	as part of the SOMS model," correct?	10	right?
11	A. That's what the recommendation	11	A. Yes.
12	was, yes.	12	Q. And, again, you echoed upstream
13	Q. Telling you that "All customers	13	that should not be telling your customers the
14	orders must be evaluated in real time against	14	reason their orders are pended, right?
15	quantity, frequency and pattern and compared to	15	MS. VANNI: Object to form.
16	orders of others in the same class of trade,"	16	THE WITNESS: Yes.
17	right?	17	BY MR. BUCHANAN:
18	A. Yes.	18	
			Q. And so you then come forward with
19	Q. And then it goes through other	19	a phased implementation process around these
20	details, some of which we've discussed, right?	20	very recommendations, right?
21	MS. VANNI: Object to form.	21	A. Similar, yes.
22	THE WITNESS: Yes.	22	Q. Well, DCT is you, right?
23	BY MR. BUCHANAN:	23	A. Yes.
24	Q. And you're saying this is one of	24	Q. That's your group?
1	the things you were looking for from them,	1	A. Drug compliance group, yes.
2	right? They had a system that would do this and		
		2	O. And this is your PowerPoint.
3		2 3	Q. And this is your PowerPoint,
3 4	you wanted to implement that system?	3	right?
4	you wanted to implement that system? A. The electronic system that would	3 4	right? A. It is, mm-hmm.
4 5	you wanted to implement that system? A. The electronic system that would tie into our order system, yes.	3 4 5	right? A. It is, mm-hmm. Q. Sent upstream to your boss,
4 5 6	you wanted to implement that system? A. The electronic system that would tie into our order system, yes. Q. Okay. They further recommended	3 4 5 6	right? A. It is, mm-hmm. Q. Sent upstream to your boss, right?
4 5 6 7	you wanted to implement that system? A. The electronic system that would tie into our order system, yes. Q. Okay. They further recommended to evaluate orders based on active ingredient	3 4 5 6 7	right? A. It is, mm-hmm. Q. Sent upstream to your boss, right? A. Yes.
4 5 6 7 8	you wanted to implement that system? A. The electronic system that would tie into our order system, yes. Q. Okay. They further recommended to evaluate orders based on active ingredient quantity rather than by dose count, right?	3 4 5 6 7 8	right? A. It is, mm-hmm. Q. Sent upstream to your boss, right? A. Yes. Q. Okay. First, let's talk about
4 5 6 7 8 9	you wanted to implement that system? A. The electronic system that would tie into our order system, yes. Q. Okay. They further recommended to evaluate orders based on active ingredient quantity rather than by dose count, right? A. Yes.	3 4 5 6 7 8	right? A. It is, mm-hmm. Q. Sent upstream to your boss, right? A. Yes. Q. Okay. First, let's talk about Phase I. Obviously, you're going to bring in
4 5 6 7 8 9	you wanted to implement that system? A. The electronic system that would tie into our order system, yes. Q. Okay. They further recommended to evaluate orders based on active ingredient quantity rather than by dose count, right? A. Yes. Q. They recommended to you to	3 4 5 6 7 8 9	right? A. It is, mm-hmm. Q. Sent upstream to your boss, right? A. Yes. Q. Okay. First, let's talk about Phase I. Obviously, you're going to bring in somebody that's going to help strengthen your
4 5 6 7 8 9 10	you wanted to implement that system? A. The electronic system that would tie into our order system, yes. Q. Okay. They further recommended to evaluate orders based on active ingredient quantity rather than by dose count, right? A. Yes. Q. They recommended to you to utilize chargeback data, right?	3 4 5 6 7 8 9 10	right? A. It is, mm-hmm. Q. Sent upstream to your boss, right? A. Yes. Q. Okay. First, let's talk about Phase I. Obviously, you're going to bring in somebody that's going to help strengthen your system of evaluating orders, right?
4 5 6 7 8 9 10 11	you wanted to implement that system? A. The electronic system that would tie into our order system, yes. Q. Okay. They further recommended to evaluate orders based on active ingredient quantity rather than by dose count, right? A. Yes. Q. They recommended to you to utilize chargeback data, right? MS. VANNI: Object to form.	3 4 5 6 7 8 9 10 11 12	right? A. It is, mm-hmm. Q. Sent upstream to your boss, right? A. Yes. Q. Okay. First, let's talk about Phase I. Obviously, you're going to bring in somebody that's going to help strengthen your system of evaluating orders, right? MS. VANNI: Object to form.
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4 5 6 7 8 9 10 11 12 13 14	you wanted to implement that system? A. The electronic system that would tie into our order system, yes. Q. Okay. They further recommended to evaluate orders based on active ingredient quantity rather than by dose count, right? A. Yes. Q. They recommended to you to utilize chargeback data, right? MS. VANNI: Object to form. THE WITNESS: Where are you seeing that? BY MR. BUCHANAN:	3 4 5 6 7 8 9 10 11 12 13 14 15	right? A. It is, mm-hmm. Q. Sent upstream to your boss, right? A. Yes. Q. Okay. First, let's talk about Phase I. Obviously, you're going to bring in somebody that's going to help strengthen your system of evaluating orders, right? MS. VANNI: Object to form. THE WITNESS: To implement the electronic system, yes. BY MR. BUCHANAN:
4 5 6 7 8 9 10 11 12 13 14 15 16	you wanted to implement that system? A. The electronic system that would tie into our order system, yes. Q. Okay. They further recommended to evaluate orders based on active ingredient quantity rather than by dose count, right? A. Yes. Q. They recommended to you to utilize chargeback data, right? MS. VANNI: Object to form. THE WITNESS: Where are you seeing that? BY MR. BUCHANAN: Q. I'm on 1052.12. Evaluate orders	3 4 5 6 7 8 9 10 11 12 13 14 15 16	right? A. It is, mm-hmm. Q. Sent upstream to your boss, right? A. Yes. Q. Okay. First, let's talk about Phase I. Obviously, you're going to bring in somebody that's going to help strengthen your system of evaluating orders, right? MS. VANNI: Object to form. THE WITNESS: To implement the electronic system, yes. BY MR. BUCHANAN: Q. Cegedim, right?
4 5 6 7 8 9 10 11 12 13 14 15 16	you wanted to implement that system? A. The electronic system that would tie into our order system, yes. Q. Okay. They further recommended to evaluate orders based on active ingredient quantity rather than by dose count, right? A. Yes. Q. They recommended to you to utilize chargeback data, right? MS. VANNI: Object to form. THE WITNESS: Where are you seeing that? BY MR. BUCHANAN: Q. I'm on 1052.12. Evaluate orders based on active ingredient quantity rather than	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	right? A. It is, mm-hmm. Q. Sent upstream to your boss, right? A. Yes. Q. Okay. First, let's talk about Phase I. Obviously, you're going to bring in somebody that's going to help strengthen your system of evaluating orders, right? MS. VANNI: Object to form. THE WITNESS: To implement the electronic system, yes. BY MR. BUCHANAN: Q. Cegedim, right? A. Yes.
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	you wanted to implement that system? A. The electronic system that would tie into our order system, yes. Q. Okay. They further recommended to evaluate orders based on active ingredient quantity rather than by dose count, right? A. Yes. Q. They recommended to you to utilize chargeback data, right? MS. VANNI: Object to form. THE WITNESS: Where are you seeing that? BY MR. BUCHANAN: Q. I'm on 1052.12. Evaluate orders based on active ingredient quantity rather than by dose count within a specific product family. The second bullet says, "Utilize chargeback data to evaluate downstream distribution of our	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	right? A. It is, mm-hmm. Q. Sent upstream to your boss, right? A. Yes. Q. Okay. First, let's talk about Phase I. Obviously, you're going to bring in somebody that's going to help strengthen your system of evaluating orders, right? MS. VANNI: Object to form. THE WITNESS: To implement the electronic system, yes. BY MR. BUCHANAN: Q. Cegedim, right? A. Yes. Q. You're going to bring them in, right? A. Correct.
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	Page 370		Page 372
1	out plans to integrate system requirements	1	A. Right.
2	between the order system and the Cegedim system	2	MS. VANNI: Form.
3	for order monitoring, right?	3	THE WITNESS: Things that were
4	A. Yes.	4	not happening by the compliance team or
5	Q. Okay. Further, in this phased	5	things that I wanted to improve.
6	approach, Phase II, you're going to look at all	6	BY MR. BUCHANAN:
7	products, not just some products, right?	7	Q. Right.
8	A. We were adding the chemicals	8	Well, certainly, here it doesn't
9	which are not required to be regulated to be	9	note that our sales force is doing on-site
10	handled in that way by DEA, but we were adding	10	customer evaluations for compliance, right?
11	them.	11	A. Didn't need to be. It was an
12	Q. You're going to start doing	12	internal document, and that was well known.
13	search trending, right?	13	Q. And next you proposed as Phase
14	A. Search	14	III accessing chargeback data, correct, ma'am?
15	Q. Sales trending?	15	A. Yes.
16	A. Sales trending.	16	Q. Before the DEA ever even told
17	Q. Yes.	17	you, right?
18	MS. VANNI: Object to form.	18	A. Correct. It was brought up at
19	THE WITNESS: Yes.	19	other conferences.
20	BY MR. BUCHANAN:	20	Q. Right. So you didn't need this
21	Q. You're going to start doing sales	21	meeting with the DEA in March to know that,
22	trending to assist with discovery of customer	22	right?
23	ordering patterns, frequencies and sizes, right?	23	A. Well, I know that other
24	A. Yes.	24	manufacturers
2 1	71. 163.	24	manufacturers
	Page 371		Page 373
1	Q. Including geographical	1	MS. VANNI: Object to form.
1 2	Q. Including geographical distributions. These are your recommendations	1 2	MS. VANNI: Object to form. THE WITNESS: were using
	distributions. These are your recommendations		
2		2	THE WITNESS: were using
2	distributions. These are your recommendations before the DEA ever sat down with you, right? A. Right, the geographical, mm-hmm,	2 3	THE WITNESS: were using chargeback data, and it was something
2 3 4	distributions. These are your recommendations before the DEA ever sat down with you, right? A. Right, the geographical, mm-hmm, yes.	2 3 4	THE WITNESS: were using chargeback data, and it was something that I was looking into.
2 3 4 5	distributions. These are your recommendations before the DEA ever sat down with you, right? A. Right, the geographical, mm-hmm, yes. Q. As somebody in the industry with	2 3 4 5	THE WITNESS: were using chargeback data, and it was something that I was looking into. BY MR. BUCHANAN:
2 3 4 5 6	distributions. These are your recommendations before the DEA ever sat down with you, right? A. Right, the geographical, mm-hmm, yes. Q. As somebody in the industry with experience in SOMS and also anti-diversion	2 3 4 5 6	THE WITNESS: were using chargeback data, and it was something that I was looking into. BY MR. BUCHANAN: Q. Right. So one of the things you were going to do is you're going to start
2 3 4 5 6 7	distributions. These are your recommendations before the DEA ever sat down with you, right? A. Right, the geographical, mm-hmm, yes. Q. As somebody in the industry with experience in SOMS and also anti-diversion efforts, right?	2 3 4 5 6 7	THE WITNESS: were using chargeback data, and it was something that I was looking into. BY MR. BUCHANAN: Q. Right. So one of the things you
2 3 4 5 6 7 8	distributions. These are your recommendations before the DEA ever sat down with you, right? A. Right, the geographical, mm-hmm, yes. Q. As somebody in the industry with experience in SOMS and also anti-diversion efforts, right? A. And sitting at DEA conferences,	2 3 4 5 6 7 8	THE WITNESS: were using chargeback data, and it was something that I was looking into. BY MR. BUCHANAN: Q. Right. So one of the things you were going to do is you're going to start accessing chargeback data and also third party
2 3 4 5 6 7 8 9	distributions. These are your recommendations before the DEA ever sat down with you, right? A. Right, the geographical, mm-hmm, yes. Q. As somebody in the industry with experience in SOMS and also anti-diversion efforts, right? A. And sitting at DEA conferences, yes.	2 3 4 5 6 7 8	THE WITNESS: were using chargeback data, and it was something that I was looking into. BY MR. BUCHANAN: Q. Right. So one of the things you were going to do is you're going to start accessing chargeback data and also third party data sources, right?
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2 3 4 5 6 7 8 9 10 11	distributions. These are your recommendations before the DEA ever sat down with you, right? A. Right, the geographical, mm-hmm, yes. Q. As somebody in the industry with experience in SOMS and also anti-diversion efforts, right? A. And sitting at DEA conferences, yes. Q. Okay. And Phase III, you're going to start doing on-site customer	2 3 4 5 6 7 8 9 10	THE WITNESS: were using chargeback data, and it was something that I was looking into. BY MR. BUCHANAN: Q. Right. So one of the things you were going to do is you're going to start accessing chargeback data and also third party data sources, right? A. IMS, yes. Q. IMS, right. This provides visibility of
2 3 4 5 6 7 8 9 10 11 12 13	distributions. These are your recommendations before the DEA ever sat down with you, right? A. Right, the geographical, mm-hmm, yes. Q. As somebody in the industry with experience in SOMS and also anti-diversion efforts, right? A. And sitting at DEA conferences, yes. Q. Okay. And Phase III, you're going to start doing on-site customer evaluations, right?	2 3 4 5 6 7 8 9 10 11 12	THE WITNESS: — were using chargeback data, and it was something that I was looking into. BY MR. BUCHANAN: Q. Right. So one of the things you were going to do is you're going to start accessing chargeback data and also third party data sources, right? A. IMS, yes. Q. IMS, right. This provides visibility of product flow down the customer stream and allows
2 3 4 5 6 7 8 9 10 11 12 13 14	distributions. These are your recommendations before the DEA ever sat down with you, right? A. Right, the geographical, mm-hmm, yes. Q. As somebody in the industry with experience in SOMS and also anti-diversion efforts, right? A. And sitting at DEA conferences, yes. Q. Okay. And Phase III, you're going to start doing on-site customer evaluations, right? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13	THE WITNESS: were using chargeback data, and it was something that I was looking into. BY MR. BUCHANAN: Q. Right. So one of the things you were going to do is you're going to start accessing chargeback data and also third party data sources, right? A. IMS, yes. Q. IMS, right. This provides visibility of product flow down the customer stream and allows for enhanced compliance for the "Know Your
2 3 4 5 6 7 8 9 10 11 12 13 14 15	distributions. These are your recommendations before the DEA ever sat down with you, right? A. Right, the geographical, mm-hmm, yes. Q. As somebody in the industry with experience in SOMS and also anti-diversion efforts, right? A. And sitting at DEA conferences, yes. Q. Okay. And Phase III, you're going to start doing on-site customer evaluations, right? A. Yes. Q. That was before you met with the	2 3 4 5 6 7 8 9 10 11 12 13 14	THE WITNESS: were using chargeback data, and it was something that I was looking into. BY MR. BUCHANAN: Q. Right. So one of the things you were going to do is you're going to start accessing chargeback data and also third party data sources, right? A. IMS, yes. Q. IMS, right. This provides visibility of product flow down the customer stream and allows for enhanced compliance for the "Know Your Customer" requirement of the DEA, correct?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	distributions. These are your recommendations before the DEA ever sat down with you, right? A. Right, the geographical, mm-hmm, yes. Q. As somebody in the industry with experience in SOMS and also anti-diversion efforts, right? A. And sitting at DEA conferences, yes. Q. Okay. And Phase III, you're going to start doing on-site customer evaluations, right? A. Yes. Q. That was before you met with the DEA, right? A. Those were things we were Q. On-site customer evaluations? A. Things we were moving towards, yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	THE WITNESS: were using chargeback data, and it was something that I was looking into. BY MR. BUCHANAN: Q. Right. So one of the things you were going to do is you're going to start accessing chargeback data and also third party data sources, right? A. IMS, yes. Q. IMS, right. This provides visibility of product flow down the customer stream and allows for enhanced compliance for the "Know Your Customer" requirement of the DEA, correct? A. I thought it would, yes. Q. Right. And so as of 2013, before you ever met with the DEA, you were aware of the know your customer obligation, correct?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	distributions. These are your recommendations before the DEA ever sat down with you, right? A. Right, the geographical, mm-hmm, yes. Q. As somebody in the industry with experience in SOMS and also anti-diversion efforts, right? A. And sitting at DEA conferences, yes. Q. Okay. And Phase III, you're going to start doing on-site customer evaluations, right? A. Yes. Q. That was before you met with the DEA, right? A. Those were things we were Q. On-site customer evaluations? A. Things we were moving towards, yes. Q. 1052.15, right?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	THE WITNESS: were using chargeback data, and it was something that I was looking into. BY MR. BUCHANAN: Q. Right. So one of the things you were going to do is you're going to start accessing chargeback data and also third party data sources, right? A. IMS, yes. Q. IMS, right. This provides visibility of product flow down the customer stream and allows for enhanced compliance for the "Know Your Customer" requirement of the DEA, correct? A. I thought it would, yes. Q. Right. And so as of 2013, before you ever met with the DEA, you were aware of the know your customer obligation, correct? MS. VANNI: Object to form.

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Page 374
                                                                                                        Page 376
                                                                              If we can go to 1071.5. We have
                                                               1
 1
        availability of chargeback data because you were
 2
        going to start to access it, right?
                                                               2
                                                                     the same graphic off to the right.
 3
                 MS. VANNI: Object to form.
                                                               3
                                                                              Do you see that?
 4
                 THE WITNESS: We were looking
                                                               4
                                                                          A. I do.
 5
            into it to see if it really provided
                                                               5
                                                                          Q. Where you've got the Quota Grant
                                                               6
 6
                                                                     Process, the Manufacturing Site Compliance, Data
            what DEA thought it did.
 7
        BY MR. BUCHANAN:
                                                               7
                                                                     Integrity and Suspicious Order Monitoring as
 8
                  And what you wrote here was Phase
                                                               8
                                                                     critical elements of DEA compliance?
 9
                                                               9
                                                                          A. Correct.
        III was to access chargeback data and third
10
        party data, right?
                                                             10
                                                                         Q. Correct? Suspicious order
11
            A.
                  Yes.
                                                             11
                                                                     monitoring we talked about that and your phrase
                                                             12
                                                                     here mirrors the one in the other document,
12
             O.
                  And we can agree this is two
13
        months before you melt with the FDA -- excuse
                                                             13
                                                                     correct?
                                                             14
14
        me -- DEA?
                                                                          A.
                                                                               Yes.
15
                                                             15
                                                                         Q. Implement a solution and
             A.
                  Yes.
16
            Q.
                  Thank you. You can set that
                                                             16
                                                                     implement a solution, correct?
17
                                                             17
                                                                              Implement a solution is what it
        aside.
18
                                                             18
                                                                     says, you must implement one.
                 (Document marked for
19
            identification as Par-Norton Deposition
                                                             19
                                                                          Q. "Implement a solution that
20
                                                             20
            Exhibit No. 16.)
                                                                     proactively discloses suspicious orders based on
21
        BY MR. BUCHANAN:
                                                             21
                                                                     unusual size, order pattern, deviation and
                                                                     unusual frequency," correct?
22
            Q. Passing you, ma'am, what we're
                                                             22
23
        marking as 1071 to your deposition -- I'm sorry.
                                                             23
                                                                          A. Yes.
24
        That's false. I'm passing you what we're
                                                             24
                                                                          Q. Okay.
                                                                                                        Page 377
                                           Page 375
 1
       marking as Exhibit 16. I've got a separate
                                                               1
                                                                           A. This is not talking about the
 2
       number on mine.
                                                               2
                                                                      current state of the business. It's talking
 3
                MR. BUCHANAN: Could we pull up
                                                               3
                                                                      about the requirements for DEA.
 4
            1071 on the screen.
                                                               4
                                                                           Q. Let's go to 1071.8.
 5
                                                               5
                                                                               There's an analysis of current
                This is an e-mail exchange --
 6
            excuse me. What exhibit did I pass you,
                                                               6
                                                                      weaknesses, right?
 7
                                                               7
           on the top right corner, is it 1052?
                                                                               Yes.
                                                                           A.
 8
                MS. VANNI: No, 1071.1.
                                                               8
                                                                           Q. Okay. Weaknesses and there's
 9
                MR. BUCHANAN: Okay. It should
                                                               9
                                                                      strengths and opportunities and threats and all
10
           be 1071. Are we on the same page? We
                                                             10
                                                                      kinds of things. I'm not going to have time to
11
                                                             11
                                                                      go through all of this with you.
            are, good.
12
                THE WITNESS: 1071.
                                                             12
                                                                               One of the weaknesses at this
13
       BY MR. BUCHANAN:
                                                             13
                                                                      point in time was you had a lack of resources,
14
            Q. Okay. This is Exhibit 16 to your
                                                             14
                                                                      right?
15
       deposition. It's an e-mail exchange between
                                                             15
                                                                           A. Yes.
       yourself and Ms. Connell again, DEA Compliance
16
                                                             16
                                                                           O.
                                                                                Limited talent pool and limited
17
       Initiative Presentation. This is from 2/9, and
                                                             17
                                                                      investments in the group, right?
18
       the attachment is "DEA Compliance Improvement
                                                             18
                                                                               MS. VANNI: Object to form.
19
       Initiative."
                                                             19
                                                                               THE WITNESS: I'm not sure what
20
                Do you see that?
                                                             20
                                                                           the investments means, to be honest, but
21
                                                             21
            A. Yes.
                                                                           the talent pool, yes.
22
            Q. Contents are on page 1071.3.
                                                             22
                                                                      BY MR. BUCHANAN:
23
       Executive summary, SWOT analysis, DEA compliance
                                                             23
                                                                           Q. Another weakness you had was a
       team and then action summaries and other things.
24
                                                             24
                                                                      "lack of training & compliance first culture,"
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	Page 378		Page 380
1	right?	1	Q. Well, we can agree it doesn't say
2	A. Yes.	2	that?
3	Q. Compliance first culture meaning	3	A. We can agree you can interpret it
4	we got to do this, it's really important that we	4	however you would like, but that's not what it
5	do it, right?	5	meant.
6	MS. VANNI: Object to form.	6	Q. What you wrote was "inadequate
7	THE WITNESS: I'm again not sure	7	SOMS," correct?
8	what first culture means. Some of those	8	A. That's what's stated there,
9	words, I have a feeling Sanjay	9	correct.
10	participated in this.	10	Q. Okay. And SOMS are suspicious
11	BY MR. BUCHANAN:	11	order monitoring systems?
12	Q. Okay. And what's the next	12	A. Yes. Inadequate means you have
13	weakness?	13	one, you just want to improve it.
14	A. "Inadequate SOMS."	14	Q. Okay. So
15	We wanted it to be stronger.	15	A. It doesn't say nonexisting.
16	Q. Let's be clear, the words you	16	Q. Inadequate means not adequate,
17	wrote were "inadequate SOMS," correct, ma'am?	17	right?
18	A. Correct. Current program is not	18	A. Not adequate by whose standards?
19	adequate for my standards.	19	By mine in this case.
20	Q. Okay. And what we're looking at	20	Q. Not adequate, correct?
21	here is could you remind us, ma'am, is this	21	A. By my standards, yes.
22	before or after you sat down with the DEA?	22	Q. That's what you were the head
23	A. This is before.	23	of DEA compliance as of this point in time,
24	Q. Okay. So even before you sat	24	correct?
	Page 379		Page 381
1	down with the DEA and spent the three hours in	1	MS. VANNI: Object to form.
2	DC with them, I mean, you knew you had	2	THE WITNESS: And I had very high
3	inadequate SOMS, right?	3	goals and standards.
		_	goals and standards.
4	MS. VANNI: Object to form.	4	BY MR. BUCHANAN:
4 5	MS. VANNI: Object to form. THE WITNESS: I knew I had		_
		4	BY MR. BUCHANAN:
5	THE WITNESS: I knew I had	4 5	BY MR. BUCHANAN: Q. And we can agree not only your
5 6	THE WITNESS: I knew I had improvements that I wanted to make.	4 5 6	BY MR. BUCHANAN: Q. And we can agree not only your standards that was inadequate by but inadequate
5 6 7	THE WITNESS: I knew I had improvements that I wanted to make. BY MR. BUCHANAN:	4 5 6 7	BY MR. BUCHANAN: Q. And we can agree not only your standards that was inadequate by but inadequate by the consultants who you met with, correct?
5 6 7 8	THE WITNESS: I knew I had improvements that I wanted to make. BY MR. BUCHANAN: Q. I understand that's how it's	4 5 6 7 8	BY MR. BUCHANAN: Q. And we can agree not only your standards that was inadequate by but inadequate by the consultants who you met with, correct? MS. VANNI: Object to form.
5 6 7 8 9	THE WITNESS: I knew I had improvements that I wanted to make. BY MR. BUCHANAN: Q. I understand that's how it's characterized here in the record, ma'am, but	4 5 6 7 8 9	BY MR. BUCHANAN: Q. And we can agree not only your standards that was inadequate by but inadequate by the consultants who you met with, correct? MS. VANNI: Object to form. THE WITNESS: Because they wanted
5 6 7 8 9	THE WITNESS: I knew I had improvements that I wanted to make. BY MR. BUCHANAN: Q. I understand that's how it's characterized here in the record, ma'am, but what you wrote to your boss is we have	4 5 6 7 8 9	BY MR. BUCHANAN: Q. And we can agree not only your standards that was inadequate by but inadequate by the consultants who you met with, correct? MS. VANNI: Object to form. THE WITNESS: Because they wanted the business, yes.
5 6 7 8 9 10 11	THE WITNESS: I knew I had improvements that I wanted to make. BY MR. BUCHANAN: Q. I understand that's how it's characterized here in the record, ma'am, but what you wrote to your boss is we have inadequate SOMS correct?	4 5 6 7 8 9 10	BY MR. BUCHANAN: Q. And we can agree not only your standards that was inadequate by but inadequate by the consultants who you met with, correct? MS. VANNI: Object to form. THE WITNESS: Because they wanted the business, yes. BY MR. BUCHANAN:
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	THE WITNESS: I knew I had improvements that I wanted to make. BY MR. BUCHANAN: Q. I understand that's how it's characterized here in the record, ma'am, but what you wrote to your boss is we have inadequate SOMS correct? MS. VANNI: Objection. THE WITNESS: That's what the document says versus what is BY MR. BUCHANAN: Q. And that's what you put into it? A. Yeah. Q. Okay. And what you forwarded up the food chain in Qualitest at that point in time, correct? MS. VANNI: Objection.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	BY MR. BUCHANAN: Q. And we can agree not only your standards that was inadequate by but inadequate by the consultants who you met with, correct? MS. VANNI: Object to form. THE WITNESS: Because they wanted the business, yes. BY MR. BUCHANAN: Q. Okay. We can agree before the DEA told you that your SOMS system was inadequate, you had concluded it was inadequate, correct? MS. VANNI: Object to form. THE WITNESS: DEA did not say the SOMS system was inadequate. If they found it to be inadequate, we would have gotten violations. We did not get
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	Page 382		Page 384
1	with regard to your system.	1	THE WITNESS: That was the goal,
2	A. You have them.	2	yes.
3	Q. And we have your statements with	3	BY MR. BUCHANAN:
4	regard to the SOM system before you sat with the	4	Q. Okay. One of your other Phase
5	DEA, correct?	5	III items was to implement, those were the words
6	A. Yes.	6	you used, right, implement?
7	Q. And you noted you had an	7	You see that?
8	inadequate SOM system, correct?	8	A. Yes.
9	THE WITNESS: That's what's	9	Q. On-site customer audits, correct?
10	written.	10	A. Correct.
11	MS. VANNI: Object to form.	11	Q. Utilizing an external audit team,
12	BY MR. BUCHANAN:	12	correct?
13	Q. We know that you met with you	13	A. That's what it says, yes, by
14	had consultants that came and then looked at	14	compliance.
15		15	O. You can set that aside.
	your system in 2013, right?		
16 17	A. Yes.	16 17	MR. BUCHANAN: Do you mind if we take an earlier break? How many minutes
	Q. Before you met with the DEA		-
18	right?	18	are we? Can we just take a break. I
19	A. Yes.	19	just need to shuffle some papers so I
20	Q. And they said it was inadequate,	20	provide appropriate time for my
21	correct?	21	co-counsel.
22	A. Inadequate by yes.	22	MS. VANNI: That's fine.
23	Q. Okay. Let's go forward to	23	THE VIDEOGRAPHER: Off the record
24	1071.20. And, regrettably, I'm not going to	24	now, it's 3:15 p m. Off the record.
	1		
1	have time to go through all of this with you	1	(Brief recess.)
1 2	have time to go through all of this with you, but I'd like to focus on action area suspicious	1 2	(Brief recess.) THE VIDEOGRAPHER: We're now back
2	but I'd like to focus on action area suspicious	2	THE VIDEOGRAPHER: We're now back
2	but I'd like to focus on action area suspicious order monitoring system.	2 3	THE VIDEOGRAPHER: We're now back on the record. The time is 3:39 p m.
2 3 4	but I'd like to focus on action area suspicious order monitoring system. Again, we see phases of the	2 3 4	THE VIDEOGRAPHER: We're now back on the record. The time is 3:39 p m. (Document marked for
2 3 4 5	but I'd like to focus on action area suspicious order monitoring system. Again, we see phases of the "Proposed Next Steps," correct?	2 3 4 5	THE VIDEOGRAPHER: We're now back on the record. The time is 3:39 p m. (Document marked for identification as Par-Norton Deposition
2 3 4 5 6	but I'd like to focus on action area suspicious order monitoring system. Again, we see phases of the "Proposed Next Steps," correct? A. Correct.	2 3 4 5 6	THE VIDEOGRAPHER: We're now back on the record. The time is 3:39 p m. (Document marked for identification as Par-Norton Deposition Exhibit No. 17.)
2 3 4 5 6 7	but I'd like to focus on action area suspicious order monitoring system. Again, we see phases of the "Proposed Next Steps," correct? A. Correct. Q. The purpose to implement a robust	2 3 4 5 6 7	THE VIDEOGRAPHER: We're now back on the record. The time is 3:39 p m. (Document marked for identification as Par-Norton Deposition Exhibit No. 17.) BY MR. BUCHANAN:
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	but I'd like to focus on action area suspicious order monitoring system. Again, we see phases of the "Proposed Next Steps," correct? A. Correct. Q. The purpose to implement a robust system to guarantee reliability and legit — in the legitimacy of our customer base, right? A. Yes. Q. And I'm just going to call to your attention "Phase III: Utilize chargeback and IMS data to 'know your customer's customer'," correct? A. That's what it says, yes. Q. Before you sat with the DEA? A. Yes. MS. VANNI: Object to form. BY MR. BUCHANAN: Q. One of the things in your phase	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	THE VIDEOGRAPHER: We're now back on the record. The time is 3:39 p m. (Document marked for identification as Par-Norton Deposition Exhibit No. 17.) BY MR. BUCHANAN: Q. Ma'am, I'm passing you over what we're marking as Exhibit 17 to your deposition. Are you miked up, ma'am? A. Yes. Q. You are. Okay. Better than I. It's a document from early 2013, right? A. Yes. Q. An e-mail from yourself to Sanjay Patel? A. Yes, correct.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	but I'd like to focus on action area suspicious order monitoring system. Again, we see phases of the "Proposed Next Steps," correct? A. Correct. Q. The purpose to implement a robust system to guarantee reliability and legit — in the legitimacy of our customer base, right? A. Yes. Q. And I'm just going to call to your attention "Phase III: Utilize chargeback and IMS data to 'know your customer's customer'," correct? A. That's what it says, yes. Q. Before you sat with the DEA? A. Yes. MS. VANNI: Object to form. BY MR. BUCHANAN: Q. One of the things in your phase planned approach here was to utilize chargeback	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	THE VIDEOGRAPHER: We're now back on the record. The time is 3:39 p m. (Document marked for identification as Par-Norton Deposition Exhibit No. 17.) BY MR. BUCHANAN: Q. Ma'am, I'm passing you over what we're marking as Exhibit 17 to your deposition. Are you miked up, ma'am? A. Yes. Q. You are. Okay. Better than I. It's a document from early 2013, right? A. Yes. Q. An e-mail from yourself to Sanjay Patel? A. Yes, correct. Q. Copied to your boss, Jill Connell? A. Yes.

	Page 386		Page 388
1	Q. Okay. This is today's meeting,	1	Q. Not good, right?
2	and then it's got a list of action items.	2	MS. VANNI: Objection.
3	Do you see that?	3	THE WITNESS: Not good.
4	A. Yes, I do.	4	BY MR. BUCHANAN:
5	Q. Okay. Let's roll forward to the	5	Q. Okay. "The system needs to be
6	body of this, and it's January 4, 2013, just to	6	revamped," right?
7	orient ourselves in time. This would have been	7	A. Yes.
8	prior to the meeting with DEA when you got that	8	Q. Remember we talked earlier about
9	thick binder that we spoke about, right?	9	the system needing to be revamped?
10	A. Yes.	10	A. Yes, improvements needed to be
11	Q. This would have been prior to the	11	made.
12	interactions you had with the Buzzeo group in	12	Q. And what you wrote was revamped,
13	mid-January 2013, right?	13	right?
14	A. Yes.	14	MS. VANNI: Object to form.
15	Q. Okay. Let's go forward to if	15	THE WITNESS: Yes.
16	we could, page 574.24, right.	16	BY MR. BUCHANAN:
17	So prior to this meeting and this	17	0 = 1 11 11 11 11
18	audit you had with Buzzeo, you were categorizing	18	Q. First, all customers have to be added, right?
19	potential failure modes and effects, visibility	19	A. Yes.
20		20	
	rating, severity rating, et cetera, right?		Q. "IMS data and chargeback data
21	A. Yes.	21	incorporated," correct?
22	Q. Okay. And so with regard to your	22	A. That's what it says, yes.
23	suspicious order monitoring system, you note	23	Q. "And eventually a contracted
24	that it was built in pieces and only applies to	24	customer assessment firm hired or an on-site
	Page 387		Page 389
1	the retail side of the business, correct, ma'am?	1	SOMS specific individual to perform these
2	A. SOMS does, yes.	2	assessments."
3	Q. Okay. The "suspicious order	3	Did I read that correctly?
4	monitoring program was built in pieces and only	4	A. Yes, you did.
5	applies to the retail side of the business."	5	Q. You knew all of that on your own
6	Did I read that correctly?	6	without having to go up to DC and meet with the
7	A. You did.	7	DEA, right?
8	Q. DEA requires it to apply to all	8	MS. VANNI: Object to form.
9	customers.	9	THE WITNESS: Yes, we were trying
10	Do you see that?	10	to make a lot of improvements before DEA
11	A. Correct, which is what we had	11	even got involved.
12	· · · · · · · · · · · · · · · · · · ·	12	BY MR. BUCHANAN:
13	Q. Your words, right? A. Yes.	13	
1.5			Q. Okay. How to revamp it, right?A. How to make improvements.
	Olympi Illia addition the account		A How to make improvements
14	Q. Okay. "In addition, the current	14	
14 15	system has had two issues in the past year that	15	Q. Okay. And previously you
14 15 16	system has had two issues in the past year that resulted in controlled product being released	15 16	Q. Okay. And previously you characterized the old system as inadequate,
14 15 16 17	system has had two issues in the past year that resulted in controlled product being released that should not have been."	15 16 17	Q. Okay. And previously you characterized the old system as inadequate, correct?
14 15 16 17 18	system has had two issues in the past year that resulted in controlled product being released that should not have been." Do you see that?	15 16 17 18	Q. Okay. And previously you characterized the old system as inadequate, correct? MS. VANNI: Object to form.
14 15 16 17 18 19	system has had two issues in the past year that resulted in controlled product being released that should not have been." Do you see that? A. Yes, I do.	15 16 17 18 19	Q. Okay. And previously you characterized the old system as inadequate, correct? MS. VANNI: Object to form. THE WITNESS: Yes.
14 15 16 17 18 19 20	system has had two issues in the past year that resulted in controlled product being released that should not have been." Do you see that? A. Yes, I do. Q. That's not good, right?	15 16 17 18 19 20	Q. Okay. And previously you characterized the old system as inadequate, correct? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN:
14 15 16 17 18 19 20 21	system has had two issues in the past year that resulted in controlled product being released that should not have been." Do you see that? A. Yes, I do. Q. That's not good, right? MS. VANNI: Object to form.	15 16 17 18 19 20 21	Q. Okay. And previously you characterized the old system as inadequate, correct? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Okay. Then we look at visibility
14 15 16 17 18 19 20 21	system has had two issues in the past year that resulted in controlled product being released that should not have been." Do you see that? A. Yes, I do. Q. That's not good, right?	15 16 17 18 19 20 21 22	Q. Okay. And previously you characterized the old system as inadequate, correct? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Okay. Then we look at visibility rating and severity rating, right?
14 15 16 17 18 19 20 21	system has had two issues in the past year that resulted in controlled product being released that should not have been." Do you see that? A. Yes, I do. Q. That's not good, right? MS. VANNI: Object to form.	15 16 17 18 19 20 21	Q. Okay. And previously you characterized the old system as inadequate, correct? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. Okay. Then we look at visibility

	Page 390		Page 392
1	a while, right?	1	Q. And not just your people, I mean
2	MS. VANNI: Object to form.	2	all Qualitest employees?
3	THE WITNESS: Yes.	3	A. To train the company.
4 .	BY MR. BUCHANAN:	4	Q. Right.
5	Q. This is one way you do a risk	5	A. It wasn't that they hadn't
6	assessment, right?	6	received any training, there just wasn't any
7	A. Yes.	7	training that was mandated by the company for
8	Q. Look at the visibility of the	8	employees and nothing on a routine basis.
9	problem, look at the severity of the problem and	9	Q. 574.29, additional failure modes
10	then give it a risk score, right?	10	and effects, again, with regard to controlled
11	A. Correct.	11	substances, this relates to checking
12	Q. And the risk score you gave this	12	registrations on orders.
13	for visibility was a 5, right?	13	Do you see that?
14	A. Yes.	14	A. Yes.
15	Q. And severity was a 5, right?	15	Q. Okay. Currently, the
16	A. Yes.	16	registrations are checked when somebody becomes
17	Q. And the total risk rating was 25,	17	a new customer, right?
18	right?	18	A. Yes.
19	A. Yes.	19	Q. And when I say "currently," I
20	Q. Highest of anything highest of	20	mean when you were writing this in early 2013?
21	any risk, right?	21	A. Yes, that's correct.
22	MS. VANNI: Objection.	22	Q. Okay. And then they were only
23	THE WITNESS: Twenty-five was the	23	done every year after that, correct?
24	highest in the document, mm-hmm.	24	A. Correct.
	Page 391		B 202
	_		Page 393
1	BY MR. BUCHANAN:	1	Q. And what was the industry
2	BY MR. BUCHANAN: Q. Thank you.	2	Q. And what was the industry standard at that point in time, ma'am?
2	BY MR. BUCHANAN: Q. Thank you. Let's go to 574.28. Potential	2 3	Q. And what was the industry standard at that point in time, ma'am? A. I don't know. I don't think
2 3 4	BY MR. BUCHANAN: Q. Thank you. Let's go to 574.28. Potential failure mode and effect, "No mandatory, routine	2 3 4	Q. And what was the industry standard at that point in time, ma'am?
2 3 4 5	BY MR. BUCHANAN: Q. Thank you. Let's go to 574.28. Potential failure mode and effect, "No mandatory, routine DEA training exists for employees handling	2 3 4 5	Q. And what was the industry standard at that point in time, ma'am? A. I don't know. I don't think everybody was using NTIS, but I don't know for sure.
2 3 4 5 6	BY MR. BUCHANAN: Q. Thank you. Let's go to 574.28. Potential failure mode and effect, "No mandatory, routine DEA training exists for employees handling controlled substances."	2 3 4 5 6	Q. And what was the industry standard at that point in time, ma'am? A. I don't know. I don't think everybody was using NTIS, but I don't know for sure. Q. Well, let's see what you wrote.
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2 3 4 5 6 7 8 9 10 11 12 13 14	BY MR. BUCHANAN: Q. Thank you. Let's go to 574.28. Potential failure mode and effect, "No mandatory, routine DEA training exists for employees handling controlled substances." Did I read that correctly? A. Yes. Q. And, again, 70% of the business of Qualitest was controlled substances, right? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. "Knowledge of DEA regulations is	2 3 4 5 6 7 8 9 10 11 12 13 14	Q. And what was the industry standard at that point in time, ma'am? A. I don't know. I don't think everybody was using NTIS, but I don't know for sure. Q. Well, let's see what you wrote. What did you write the industry standard was at that point in time? A. "Industry standard is now to check the DEA license at each purchase since shipping to an entity that has an expired or invalid license is a \$10,000 fine." Q. Okay. And then you note, "The capability exists to automate this check at the
2 3 4 5 6 7 8 9 10 11 12 13 14 15	BY MR. BUCHANAN: Q. Thank you. Let's go to 574.28. Potential failure mode and effect, "No mandatory, routine DEA training exists for employees handling controlled substances." Did I read that correctly? A. Yes. Q. And, again, 70% of the business of Qualitest was controlled substances, right? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. "Knowledge of DEA regulations is not incorporated into employee's job	2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. And what was the industry standard at that point in time, ma'am? A. I don't know. I don't think everybody was using NTIS, but I don't know for sure. Q. Well, let's see what you wrote. What did you write the industry standard was at that point in time? A. "Industry standard is now to check the DEA license at each purchase since shipping to an entity that has an expired or invalid license is a \$10,000 fine." Q. Okay. And then you note, "The capability exists to automate this check at the weekly level (NTIS Tape or Database)" and "We
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	BY MR. BUCHANAN: Q. Thank you. Let's go to 574.28. Potential failure mode and effect, "No mandatory, routine DEA training exists for employees handling controlled substances." Did I read that correctly? A. Yes. Q. And, again, 70% of the business of Qualitest was controlled substances, right? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. "Knowledge of DEA regulations is not incorporated into employee's job descriptions or performance reviews," correct?	2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. And what was the industry standard at that point in time, ma'am? A. I don't know. I don't think everybody was using NTIS, but I don't know for sure. Q. Well, let's see what you wrote. What did you write the industry standard was at that point in time? A. "Industry standard is now to check the DEA license at each purchase since shipping to an entity that has an expired or invalid license is a \$10,000 fine." Q. Okay. And then you note, "The capability exists to automate this check at the weekly level (NTIS Tape or Database)" and "We need to check registrations more frequently,"
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	BY MR. BUCHANAN: Q. Thank you. Let's go to 574.28. Potential failure mode and effect, "No mandatory, routine DEA training exists for employees handling controlled substances." Did I read that correctly? A. Yes. Q. And, again, 70% of the business of Qualitest was controlled substances, right? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. "Knowledge of DEA regulations is not incorporated into employee's job descriptions or performance reviews," correct? A. Correct. Q. At this point in time, resources were prohibitive to train all employees, right?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. And what was the industry standard at that point in time, ma'am? A. I don't know. I don't think everybody was using NTIS, but I don't know for sure. Q. Well, let's see what you wrote. What did you write the industry standard was at that point in time? A. "Industry standard is now to check the DEA license at each purchase since shipping to an entity that has an expired or invalid license is a \$10,000 fine." Q. Okay. And then you note, "The capability exists to automate this check at the weekly level (NTIS Tape or Database)" and "We need to check registrations more frequently," right? A. Yes, that's what I wanted. Q. Does this refresh your memory as
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	BY MR. BUCHANAN: Q. Thank you. Let's go to 574.28. Potential failure mode and effect, "No mandatory, routine DEA training exists for employees handling controlled substances." Did I read that correctly? A. Yes. Q. And, again, 70% of the business of Qualitest was controlled substances, right? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. "Knowledge of DEA regulations is not incorporated into employee's job descriptions or performance reviews," correct? A. Correct. Q. At this point in time, resources were prohibitive to train all employees, right? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. And what was the industry standard at that point in time, ma'am? A. I don't know. I don't think everybody was using NTIS, but I don't know for sure. Q. Well, let's see what you wrote. What did you write the industry standard was at that point in time? A. "Industry standard is now to check the DEA license at each purchase since shipping to an entity that has an expired or invalid license is a \$10,000 fine." Q. Okay. And then you note, "The capability exists to automate this check at the weekly level (NTIS Tape or Database)" and "We need to check registrations more frequently," right? A. Yes, that's what I wanted. Q. Does this refresh your memory as to what you characterized the industry standard
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY MR. BUCHANAN: Q. Thank you. Let's go to 574.28. Potential failure mode and effect, "No mandatory, routine DEA training exists for employees handling controlled substances." Did I read that correctly? A. Yes. Q. And, again, 70% of the business of Qualitest was controlled substances, right? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. "Knowledge of DEA regulations is not incorporated into employee's job descriptions or performance reviews," correct? A. Correct. Q. At this point in time, resources were prohibitive to train all employees, right? A. Yes. Q. Okay. And one of the things you	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. And what was the industry standard at that point in time, ma'am? A. I don't know. I don't think everybody was using NTIS, but I don't know for sure. Q. Well, let's see what you wrote. What did you write the industry standard was at that point in time? A. "Industry standard is now to check the DEA license at each purchase since shipping to an entity that has an expired or invalid license is a \$10,000 fine." Q. Okay. And then you note, "The capability exists to automate this check at the weekly level (NTIS Tape or Database)" and "We need to check registrations more frequently," right? A. Yes, that's what I wanted. Q. Does this refresh your memory as to what you characterized the industry standard to be?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MR. BUCHANAN: Q. Thank you. Let's go to 574.28. Potential failure mode and effect, "No mandatory, routine DEA training exists for employees handling controlled substances." Did I read that correctly? A. Yes. Q. And, again, 70% of the business of Qualitest was controlled substances, right? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. "Knowledge of DEA regulations is not incorporated into employee's job descriptions or performance reviews," correct? A. Correct. Q. At this point in time, resources were prohibitive to train all employees, right? A. Yes. Q. Okay. And one of the things you were doing was to look for some funding so you	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. And what was the industry standard at that point in time, ma'am? A. I don't know. I don't think everybody was using NTIS, but I don't know for sure. Q. Well, let's see what you wrote. What did you write the industry standard was at that point in time? A. "Industry standard is now to check the DEA license at each purchase since shipping to an entity that has an expired or invalid license is a \$10,000 fine." Q. Okay. And then you note, "The capability exists to automate this check at the weekly level (NTIS Tape or Database)" and "We need to check registrations more frequently," right? A. Yes, that's what I wanted. Q. Does this refresh your memory as to what you characterized the industry standard to be? A. It does, yes.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY MR. BUCHANAN: Q. Thank you. Let's go to 574.28. Potential failure mode and effect, "No mandatory, routine DEA training exists for employees handling controlled substances." Did I read that correctly? A. Yes. Q. And, again, 70% of the business of Qualitest was controlled substances, right? MS. VANNI: Object to form. THE WITNESS: Yes. BY MR. BUCHANAN: Q. "Knowledge of DEA regulations is not incorporated into employee's job descriptions or performance reviews," correct? A. Correct. Q. At this point in time, resources were prohibitive to train all employees, right? A. Yes. Q. Okay. And one of the things you	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. And what was the industry standard at that point in time, ma'am? A. I don't know. I don't think everybody was using NTIS, but I don't know for sure. Q. Well, let's see what you wrote. What did you write the industry standard was at that point in time? A. "Industry standard is now to check the DEA license at each purchase since shipping to an entity that has an expired or invalid license is a \$10,000 fine." Q. Okay. And then you note, "The capability exists to automate this check at the weekly level (NTIS Tape or Database)" and "We need to check registrations more frequently," right? A. Yes, that's what I wanted. Q. Does this refresh your memory as to what you characterized the industry standard to be?

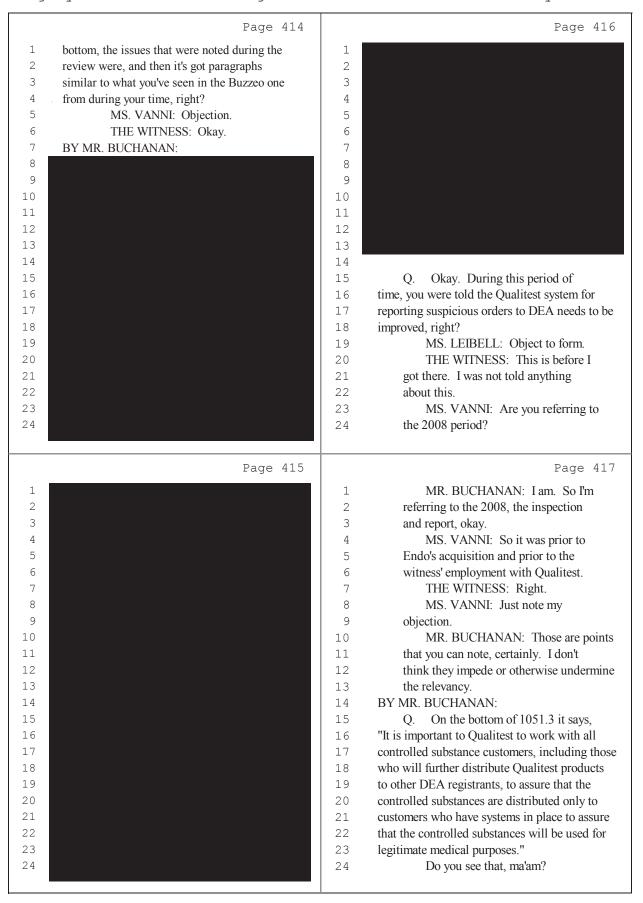
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Page 396
                                           Page 394
                                                                     might be there when there's a DEA inspection of
       were already using the NTIS data, right --
                                                              1
 1
 2
                                                              2
                                                                     a manufacturing facility, for example, right?
            A.
                  They did.
 3
            O.
                 -- back in the '80s and '90s?
                                                              3
                                                                              Correct, and I would summarize
 4
                                                              4
            A.
                  They did.
                                                                     each day.
 5
                  And when you were at Watson, they
                                                              5
                                                                              Right. And so you'd send around
            Q.
 6
                                                              6
                                                                     a report to the team or management about the
       were using, it right?
 7
                 Yes.
                                                              7
                                                                     results of the inspection, right?
            A.
                                                              8
 8
            Q.
                  And in this 2012, 2013 period you
                                                                         A.
                                                                              Yes.
 9
                                                              9
       had the situation where controlled substances
                                                                               Okay. And so this was an
                                                                         Q.
10
       were released to customers who should not -- who
                                                             10
                                                                     inspection of a manufacturing facility as the
11
       they should not have been released to, correct?
                                                             11
                                                                     primary purpose, correct?
12
                 MS. VANNI: Object to form.
                                                             12
                                                                         A. In Charlotte, yes.
13
                                                            13
                 THE WITNESS: That was not -- I
                                                                              And you'd had an issue with
14
                                                             14
                                                                     Charlotte previously, right?
            don't believe that was in relation to
15
                                                             15
                                                                              MS. VANNI: Object to form.
            their license.
                                                             16
                                                                              THE WITNESS: Yes, it was
16
       BY MR. BUCHANAN:
                                                            17
17
                  Oh, okay. What was it in
            Q.
                                                                         manufacturing.
18
                                                             18
       relation to?
                                                                     BY MR. BUCHANAN:
19
                I don't know if it was -- I don't
                                                             19
                                                                         Q. And, basically, you had raw
            A.
20
                                                             20
       know why. I need to go back to see it.
                                                                     material that was unaccounted for.
21
            Q.
                  Sitting here, do you have a
                                                             21
                                                                              Do you remember that?
22
       recollection?
                                                             22
                                                                              MS. VANNI: Object to form.
23
                                                             23
                                                                              THE WITNESS: I do not, but if
                 I do not.
            A.
                                                             24
24
                  If you don't, I'm sorry, I'm just
                                                                         you give me a minute, I'll look at this.
            O.
                                          Page 395
                                                                                                       Page 397
 1
       going to do my best to move along.
                                                              1
                                                                     BY MR. BUCHANAN:
 2
            A.
                  Okay.
                                                              2
                                                                          Q. Okay. Let me just try to keep us
 3
                  Because I try not to go down too
                                                              3
                                                                     focused, I'm sorry, if that's going to require
       many forks in the road, if you don't mind.
                                                                     you to go elsewhere.
 4
                                                              4
 5
                                                              5
                                                                               Okay.
            A. Got it.
                                                                          A.
 6
            O.
                 All right. So let's dial back
                                                              6
                                                                          O.
                                                                               567.2, middle of the second page,
 7
                                                              7
       the clock, if we could.
                                                                     and there's this discussion here with the
 8
                 MR. BUCHANAN: Could I have 567.
                                                              8
                                                                     paragraph beginning he noted about, you know,
                                                              9
 9
                 (Document marked for
                                                                     material not being accounted for, you know, if
10
            identification as Par-Norton Deposition
                                                             10
                                                                     you have .15% that's not accounted for, given
11
            Exhibit No. 18.)
                                                             11
                                                                     the volume of controlled substances y'all were
12
       BY MR. BUCHANAN:
                                                             12
                                                                     making and that turns into 130 pounds worth of
13
                                                             13
                                                                     raw material, controlled substances, right?
            Q. Passing you what we're marking as
14
       Exhibit 18 to your deposition, ma'am. It's an
                                                             14
                                                                              MS. VANNI: Object to form.
15
       exchange, it looks like right after you get to
                                                             15
                                                                              THE WITNESS: Mm-hmm.
16
       the company in 2011. It's 567. It should be on
                                                             16
                                                                     BY MR. BUCHANAN:
17
                                                             17
                                                                          Q. So you've got 130 pounds of raw
       the screen, hopefully.
18
                 You see this e-mail exchange
                                                             18
                                                                     materials that aren't accounted for, and you
19
       between yourself and others relating to a DEA
                                                             19
                                                                     guys need to tighten up your process to make
20
       inspection at one of your facilities?
                                                             20
                                                                     sure 130 pounds of -- this says 64 kilograms,
21
            A. Yes, I do.
                                                             21
                                                                     that's, you know -- that's about 130 pounds,
22
                 Okay. Let's -- I'd like to
                                                             22
                                                                     right?
23
       direct your attention -- this is one of the
                                                             23
                                                                               Calculation.
                                                                          A.
24
       things you would do with DEA compliance. You
                                                             24
                                                                               Okay. 135, something like that?
```

	Page 398		Page 400
1	A. Mm-hmm.	1	A. I do.
2	Q. Okay. He went on to say that	2	Q. And do you agree, ma'am, that as
3	"manufacturers are making larger batch sizes and	3	a registrant manufacturer and a registrant
4	greater quantities of controlled product than in	4	distributor that you have the public's trust in
5	years past," right?	5	your hands?
6	A. Yes.	6	MS. VANNI: Object to form.
7	Q. I mean, you guys were making a	7	THE WITNESS: We have a
8	lot of pills, no debate about that, right?	8	responsibility to abide by the
9	MS. VANNI: Object to form.	9	regulations, the DEA regulations.
10	THE WITNESS: That is what it	10	BY MR. BUCHANAN:
11	says.	11	Q. Right. You have a responsibility
12	BY MR. BUCHANAN:	12	under the statute to maintain effective controls
13	Q. It says, "DEA is seeing a much	13	against diversion?
14	higher rate of prescription drug abuse and	14	A. Right.
15	diversion as compared to illicit drugs now."	15	•
16	Do you see that?		
17	A. Yes.	16 17	public, knowing that you have that obligation, for assuming that you were going to do
18		18	
	Q. Higher rate of prescription drug		everything in your power to maintain effective
19	abuse and diversion as compared to illicit drugs	19	controls against diversion?
20	now, and now being 2011, right?	20	MS. VANNI: Objection.
21	A. Yes.	21	THE WITNESS: That is what we
22	Q. And this is a couple years	22	did.
23	before	23	BY MR. BUCHANAN:
24	A. Yes.	24	Q. Would you fault people for
	Page 399		Page 401
1	Q. Thank you.	1	expecting that of you?
2	It's a couple years before you	2	MS. VANNI: Objection.
3	had that sit down with the DEA where you got	3	THE WITNESS: No.
4	called into DC, right?	4	BY MR. BUCHANAN:
5	A. Yes.	5	Q. That's what you should do, right?
6	MS. VANNI: Object to form.	6	MS. VANNI: Objection.
7	BY MR. BUCHANAN:	7	THE WITNESS: Yes.
8	Q. Okay. So you had that knowledge	8	BY MR. BUCHANAN:
9	certainly in 2011, right, ma'am?	9	Q. And let's turn now to the next
10	MS. VANNI: Object to form.	10	page, point three, it says, "DEA then spoke
	THE WITNESS: Yes.	11	about SOMS at length and also discussed the need
11			
11 12			
12	BY MR. BUCHANAN:	12	to monitor customers (wholesalers in
12 13	BY MR. BUCHANAN: Q. Okay. He stated he states,	12 13	to monitor customers (wholesalers in particular), including our wholesaler's
12 13 14	BY MR. BUCHANAN: Q. Okay. He stated he states, "Yet, in his opinion, nothing has changed on the	12 13 14	to monitor customers (wholesalers in particular), including our wholesaler's customers, through periodic audits or on-site
12 13 14 15	BY MR. BUCHANAN: Q. Okay. He stated he states, "Yet, in his opinion, nothing has changed on the manufacturer's side in regards to the way we do	12 13 14 15	to monitor customers (wholesalers in particular), including our wholesaler's customers, through periodic audits or on-site visits," correct?
12 13 14 15 16	BY MR. BUCHANAN: Q. Okay. He stated he states, "Yet, in his opinion, nothing has changed on the manufacturer's side in regards to the way we do reconciliations."	12 13 14 15 16	to monitor customers (wholesalers in particular), including our wholesaler's customers, through periodic audits or on-site visits," correct? A. Yes.
12 13 14 15 16 17	BY MR. BUCHANAN: Q. Okay. He stated he states, "Yet, in his opinion, nothing has changed on the manufacturer's side in regards to the way we do reconciliations." Do you see that?	12 13 14 15 16 17	to monitor customers (wholesalers in particular), including our wholesaler's customers, through periodic audits or on-site visits," correct? A. Yes. Q. "This is not something we are
12 13 14 15 16 17	BY MR. BUCHANAN: Q. Okay. He stated he states, "Yet, in his opinion, nothing has changed on the manufacturer's side in regards to the way we do reconciliations." Do you see that? A. Yes, I do.	12 13 14 15 16 17 18	to monitor customers (wholesalers in particular), including our wholesaler's customers, through periodic audits or on-site visits," correct? A. Yes. Q. "This is not something we are currently doing and another item we will need to
12 13 14 15 16 17 18	BY MR. BUCHANAN: Q. Okay. He stated he states, "Yet, in his opinion, nothing has changed on the manufacturer's side in regards to the way we do reconciliations." Do you see that? A. Yes, I do. Q. "He stated that we have the	12 13 14 15 16 17 18 19	to monitor customers (wholesalers in particular), including our wholesaler's customers, through periodic audits or on-site visits," correct? A. Yes. Q. "This is not something we are currently doing and another item we will need to work on improving."
12 13 14 15 16 17 18 19 20	BY MR. BUCHANAN: Q. Okay. He stated he states, "Yet, in his opinion, nothing has changed on the manufacturer's side in regards to the way we do reconciliations." Do you see that? A. Yes, I do. Q. "He stated that we have the public's trust in our hands and we need to be	12 13 14 15 16 17 18 19 20	to monitor customers (wholesalers in particular), including our wholesaler's customers, through periodic audits or on-site visits," correct? A. Yes. Q. "This is not something we are currently doing and another item we will need to work on improving." Did I read that correctly?
12 13 14 15 16 17 18 19 20 21	BY MR. BUCHANAN: Q. Okay. He stated he states, "Yet, in his opinion, nothing has changed on the manufacturer's side in regards to the way we do reconciliations." Do you see that? A. Yes, I do. Q. "He stated that we have the public's trust in our hands and we need to be sure we are staying ahead of the curve by	12 13 14 15 16 17 18 19 20 21	to monitor customers (wholesalers in particular), including our wholesaler's customers, through periodic audits or on-site visits," correct? A. Yes. Q. "This is not something we are currently doing and another item we will need to work on improving." Did I read that correctly? A. You did.
12 13 14 15 16 17 18 19 20 21 22	BY MR. BUCHANAN: Q. Okay. He stated he states, "Yet, in his opinion, nothing has changed on the manufacturer's side in regards to the way we do reconciliations." Do you see that? A. Yes, I do. Q. "He stated that we have the public's trust in our hands and we need to be sure we are staying ahead of the curve by monitoring current diversion trends and	12 13 14 15 16 17 18 19 20 21 22	to monitor customers (wholesalers in particular), including our wholesaler's customers, through periodic audits or on-site visits," correct? A. Yes. Q. "This is not something we are currently doing and another item we will need to work on improving." Did I read that correctly? A. You did. Q. And so two years or so before
12 13 14 15 16 17 18 19 20 21	BY MR. BUCHANAN: Q. Okay. He stated he states, "Yet, in his opinion, nothing has changed on the manufacturer's side in regards to the way we do reconciliations." Do you see that? A. Yes, I do. Q. "He stated that we have the public's trust in our hands and we need to be sure we are staying ahead of the curve by	12 13 14 15 16 17 18 19 20 21	to monitor customers (wholesalers in particular), including our wholesaler's customers, through periodic audits or on-site visits," correct? A. Yes. Q. "This is not something we are currently doing and another item we will need to work on improving." Did I read that correctly? A. You did.

	Page 402		Page 404
1	monitor your customers, wholesalers in	1	on-site visits that this is not something you
2	particular, but including your wholesaler's	2	were currently doing, right?
3	customers, right?	3	A. Not something we were currently
4	MS. VANNI: Object to form.	4	doing under SOMS.
5	THE WITNESS: Yes, and we were	5	Q. That's not what you wrote. We
6	not as part of SOMS, we were as part of	6	can agree on that, right?
7	OMS, at least the wholesalers.	7	MS. VANNI: Objection.
8	BY MR. BUCHANAN:	8	THE WITNESS: That's not what's
9	Q. Okay. And it would be fair to	9	written.
10	say, ma'am, sitting here today, you're not aware	10	BY MR. BUCHANAN:
11	of a single site visit report of wholesaler that	11	Q. And what you follow with that is
12	was done through OMS, right?	12	"another item we will need to work on
13	MS. VANNI: Objection.	13	improving."
14	THE WITNESS: I am not, but that	14	Did I read that correctly?
15	doesn't mean they didn't occur.	15	A. You did.
16	BY MR. BUCHANAN:	16	Q. An item you will need to work on
17	Q. Okay. And we looked at the	17	improving. Not that we're doing it through
18	inadequate the inadequacies of the system	18	customer service, right?
19	A. We looked at	19	MS. VANNI: Objection.
20		20	THE WITNESS: No, that's not what
	Q in your earlier documents. Do	21	· · · · · · · · · · · · · · · · · · ·
21 22	you recall looking at that?	22	it says. I didn't elaborate.
	MS. VANNI: Object to form.		BY MR. BUCHANAN:
23	THE WITNESS: The improvements	23	Q. Not that you were doing it
24	we'd like to make, yes.	24	through sales?
	Page 403		
	1 490 100		Page 405
1		1	-
1 2	BY MR. BUCHANAN:	1 2	MS. VANNI: Objection.
2	BY MR. BUCHANAN: Q. I think you called them	2	MS. VANNI: Objection. THE WITNESS: This group is the
2	BY MR. BUCHANAN: Q. I think you called them inadequacies, right?	2 3	MS. VANNI: Objection. THE WITNESS: This group is the manufacturing group. I would not have
2 3 4	BY MR. BUCHANAN: Q. I think you called them inadequacies, right? A. In the document.	2 3 4	MS. VANNI: Objection. THE WITNESS: This group is the manufacturing group. I would not have gone into detail about our SOM program
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2 3 4 5 6	BY MR. BUCHANAN: Q. I think you called them inadequacies, right? A. In the document. Q. Yes. A. But it means improvements.	2 3 4 5 6	MS. VANNI: Objection. THE WITNESS: This group is the manufacturing group. I would not have gone into detail about our SOM program with that group. BY MR. BUCHANAN:
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2 3 4 5 6 7 8	BY MR. BUCHANAN: Q. I think you called them inadequacies, right? A. In the document. Q. Yes. A. But it means improvements. Q. Well, let's not talk about what you say it means today. Let's talk about what	2 3 4 5 6 7 8	MS. VANNI: Objection. THE WITNESS: This group is the manufacturing group. I would not have gone into detail about our SOM program with that group. BY MR. BUCHANAN: Q. Right, and, certainly, what you said was it's not something you're currently
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MR. BUCHANAN: Q. I think you called them inadequacies, right? A. In the document. Q. Yes. A. But it means improvements. Q. Well, let's not talk about what you say it means today. Let's talk about what you wrote. You wrote inadequate, correct? MS. VANNI: Objection. THE WITNESS: I did. BY MR. BUCHANAN: Q. Thank you. And you said this is not something we are currently doing, right? A. Not in SOMS. Q. What you wrote here, ma'am, after the DEA spoke about SOMS at length and also discussed the need to monitor customers,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MS. VANNI: Objection. THE WITNESS: This group is the manufacturing group. I would not have gone into detail about our SOM program with that group. BY MR. BUCHANAN: Q. Right, and, certainly, what you said was it's not something you're currently doing? We could agree that's what you wrote, correct? A. That is what it says. MS. VANNI: Objection, asked and answered now about ten times. MR. BUCHANAN: Okay. Let's go to I don't think it was ten, but it may have been more than one. THE WITNESS: Nine and a half. MR. BUCHANAN: Let's go to 1046. (Document marked for identification as Par-Norton Deposition Exhibit No. 19.) BY MR. BUCHANAN:
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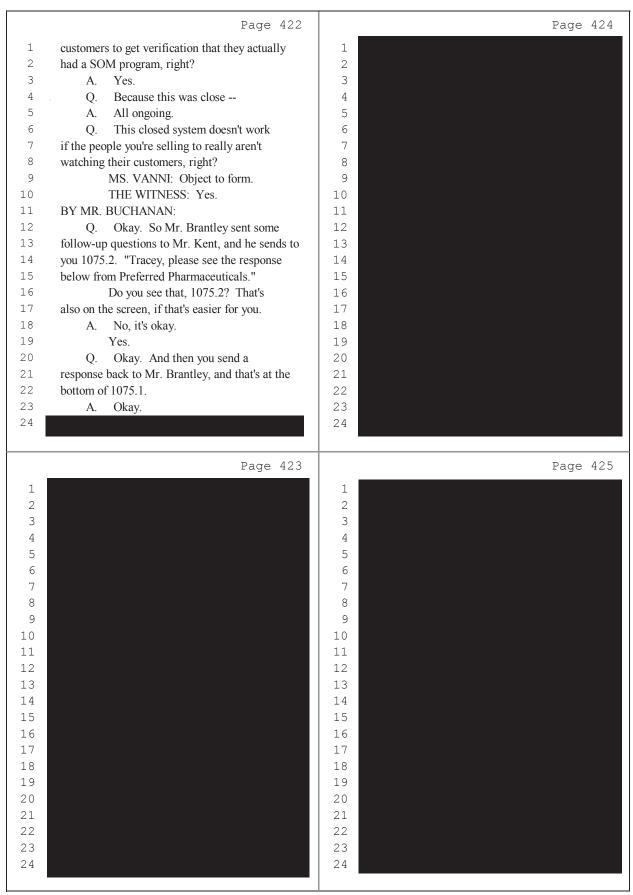
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1	working back in time, if you can follow where	1	Did I read that correctly?
2	we're going, ma'am. We first we just looked	2	A. "We just need to do our due
3	at an early 2013 exchange where you had a 25	3	diligence to find out what happens," yes.
4	risk assessment for your SOMS program.	4	Q. Right. "We just need to do our
5	Do you recall that?	5	due diligence to find out what happens to our
6	A. Yes.	6	product beyond the first level of the supply
7	Q. Twenty-five being the worst,	7	chain," right?
8	right?	8	A. For this particular customer,
9	A. Being yes, the highest	9	yes, that's what I'm referring to.
10	priority	10	Q. So your supply chain, your supply
11	MS. VANNI: Object to form.	11	chain first level would be wholesalers
12	THE WITNESS: that I want to	12	distributors, right?
13	work on.	13	A. Yes.
14	BY MR. BUCHANAN:	14	Q. Supply chain beyond the first
15	Q. Yeah, and then we also looked at	15	level would be the people they sell to, right?
16	kind of that your closeout memo from that DEA	16	A. Correct.
17	inspection in Charlotte. That was 2011, right?	17	Q. People they sell to might be
18	A. Mm-hmm, yes.	18	pharmacies, might be hospitals, any number of
19	Q. Yes?	19	places, right?
20	A. Yes.	20	A. Yes.
21	Q. I'm a little out of sequence	21	Q. And so with this saying you got
22	here. This one is September 2012. For the	22	to do your due diligence to find out what
23	record, I think we're on Exhibit 19.	23	happens to your product beyond the first level
24	And this is an e-mail from	24	of the supply chain, right?
			Page 409
1	yourself to Eric Bonner. Who is Eric Bonner?	1	A. Yes.
2	A. That's our was the plant	2	Q. Because the DEA is no longer
3	manager.	3	buying that it's not you?
4	Q. Okay. And there's a press	4	MS. VANNI: Object to form.
5	release that's out there about CVS retailers and	5	BY MR. BUCHANAN:
6	their ability to sell controlled substances,	6	Q. Right?
7	right?	7	A. I'm not getting what you're
8	A. Yes.	8	referring to.
9	Q. Okay. And you're directing them	9	Q. Withdrawn, okay.
10	to take make sure that they get taken out of	10	The DEA is no longer buying what
11	the order system, okay?	11	you all have been selling for years, right?
12	A. Right.	12	MS. VANNI: Objection.
13	Q. Because they don't have licenses	13	THE WITNESS: No.
14	anymore, right?	14	BY MR. BUCHANAN:
15	A. That's what we would do if DEA	15	Q. What you all have been selling
16	had an issue with a customer, yes.	16	for years was it wasn't us, it was our customer?
17	Q. Right. So now you couldn't	17	A. We don't sell
18	legally sell to somebody who doesn't have a	18	MS. VANNI: Objection.
19	registration, right?	19	THE WITNESS: anything to DEA.
	A. That's true.	20	BY MR. BUCHANAN:
20		21	Q. Well, I'm saying okay. Let's
20 21	Q. Okay. And then up top you say,		The state of the s
	we need our due diligence to find out what	22	look at what you wrote, ma'am.
21			The state of the s

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1	statement.	1	BY MR. BUCHANAN:
2	Q. I'm referring to what you wrote	2	Q. Okay. So, as I understand it,
3	in the middle, September 12, 2012, if we ship to	3	Qualitest was acquired by Endo, correct?
4	a distribution center that's what DC means,	4	A. Correct.
5	right?	5	Q. You joined Qualitest in 2011?
6	A. Yes.	6	A. Yes.
7	Q. Okay. "That then further	7	Q. As part of your evaluation and
8	distributes to these registrants, we are still	8	role I'm sorry as part of your role in DEA
9	shipping to an entity that is contributing to	9	compliance, did you look to see did you
10	diversion and abuse as evidenced by DEA pulling	10	evaluate the department?
11	their license."	11	A. Yes.
12	Did I read that correctly?	12	MS. KOSKI: Object to form.
13	A. Yes.	13	THE WITNESS: To what extent?
14		14	
	Q. "DEA is no longer buying the"		What are you referring to specifically
15	and then you put in quotes "it wasn't us, it	15	did I evaluate?
16	was our customer philosophy," right?	16	BY MR. BUCHANAN:
17	A. Yes, and that's	17	Q. Well, would it surprise you that,
18	Q. I'm sorry. That's what you	18	in fact, Qualitest had other consultants come in
19	wrote, correct?	19	years before you arrived and look at their
20	A. Yes, that's what I wrote.	20	suspicious order monitoring system?
21	MR. BUCHANAN: Can I have 1051,	21	MS. VANNI: Objection.
22	please.	22	THE WITNESS: I don't know.
23	(Document marked for	23	BY MR. BUCHANAN:
24	identification as Par-Norton Deposition	24	Q. Okay. Here's a here is one
1	Page 411	1	Page 413
1 2	Exhibit No. 20.) BY MR. BUCHANAN:	1 2	such evaluation from 2008. Do you know John Schultz?
3		3	
4	Q. And that was 2011 2012, excuse me?	4	
		5	Q. Who is John?
5 6	A. 2012.		A. He had the position before me.
	Q. So, again, once again, before you	6	Q. Okay. So he was predecessor. He
7	met with the DEA and had that sit down, right?	7	didn't have the name of head of DEA compliance,
8	A. Yes, to individuals that wouldn't	8	but he had a similar function?
9	understand the SOM program. These are basically	9	MS. VANNI: Object to form.
10	operations people, so that's why it was worded	10	THE WITNESS: I'm not sure his
11	that way.	11	title.
12	Q. Passing you, ma'am, what we've	12	BY MR. BUCHANAN:
13	marked as Exhibit 20 to your I'm sorry, is	13	Q. Okay. "All, attached is Mike's
14	this 20? Twenty. Let me read your sticker on	14	audit report from his visit. We will need to
15	the bottom right, ma'am.	15	formulate a response and implement the
16	A. Exhibit 20.	16	corrective actions. Please provide comment on
17	Q. I did do that right. Exhibit 20.	17	the observations with suggested corrective
18	MS. VANNI: I just want to lodge	18	actions."
19	an objection to the use of this exhibit	19	Did I read that correctly?
20	as it's before Endo's acquisition of	20	A. Yes.
21	Qualitest.	21	Q. Okay. And, time permitting, we
22	MR. BUCHANAN: Okay.	22	would get more deeply into this, but let's focus
23	THE WITNESS: Yeah, and before my	23	on the thread we're now talking about, 1051.2.
24	time at Qualitest as well.	24	Under the "Details" at the
23	THE WITNESS: Yeah, and before my	23	on the thread we're now talking about, 1051.2

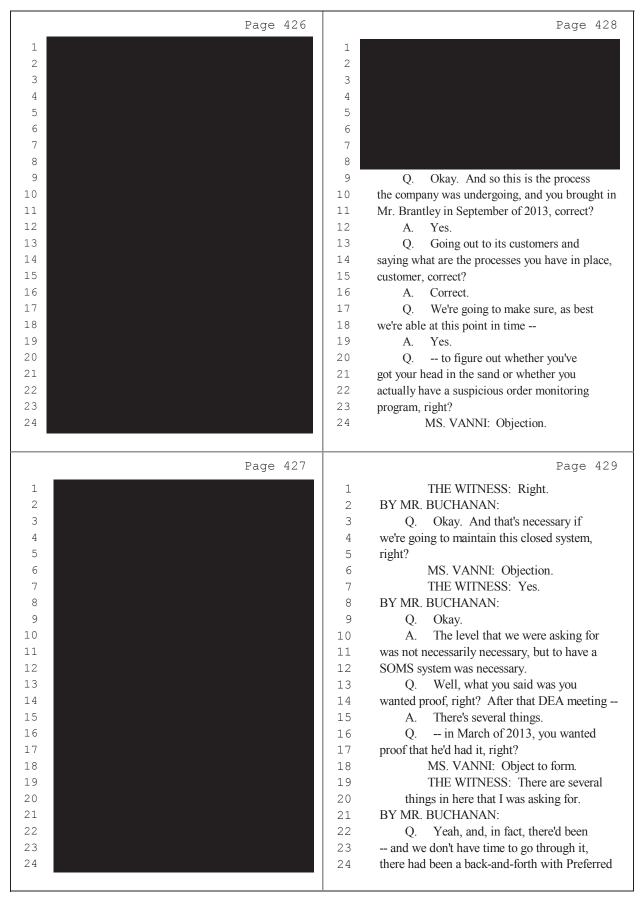


105 (Pages 414 to 417)

	Page 418		Page 420
1	A. I see it.	1	(Document marked for
2	Q. And this is 2008, correct?	2	identification as Par-Norton Deposition
3	A. That's the date on it.	3	Exhibit No. 21.)
4	Q. You can set that aside.	4	BY MR. BUCHANAN:
5	A. Again, I had no knowledge of it	5	Q. Passing you what we're marking as
6	and wasn't involved.	6	Exhibit 21 to your deposition, ma'am, it's an
7	Q. Okay. And, again, we looked at a	7	exchange with you and your SOMS coordinator,
8	letter from Mr. Rannazzisi in a PowerPoint.	8	Mr. Brantley.
9	Do you recall that?	9	A. Okay.
10	A. Yes.	10	Q. This is from late 2014 or October
11	Q. That was from 2007?	11	of 2014, and I guess if you start back forward,
12	A. Correct.	12	you'll see an exchange between Mr. Brantley and
13	Q. Okay. Let's try and move	13	Mr. Kent with his att net e-mail address for
14	forward.	14	Preferred Pharmaceuticals in response to
15	In late 2013 the company revamped	15	Mr. Brantley's inquiries.
16	its SOMS process and implemented new SOPs, fair?	16	Do you see that?
17	MS. VANNI: Object to form.	17	A. I do.
18	THE WITNESS: Upgraded the	18	Q. Okay.
19	program, yes.	19	MR. BUCHANAN: Please, Bradley,
20	BY MR. BUCHANAN:	20	go to 1075.4, just so we're following
21	Q. And I don't think we'll have time	21	each other on the screen.
22	to go through those SOPs with you, but I would	22	BY MR. BUCHANAN:
23	like to talk to you about some of the responses	23	Q. All right. There we go, we see
24	you received to the dear customer letter, the	24	the e-mail from Mr. Kent for Preferred
24	you received to the dear customer letter, the	24	the e-man from Mr. Kent for Freiened
	Page 419		
	rage 419		Page 421
1	responses you didn't receive, okay?	1	Page 421 Pharmaceuticals, and Mr. Brantley is having a
1 2		1 2	Pharmaceuticals, and Mr. Brantley is having a
	responses you didn't receive, okay?		Pharmaceuticals, and Mr. Brantley is having a back-and-forth with them concerning his part
2	responses you didn't receive, okay? A. Okay. MR. BUCHANAN: Can I have 1075,	2	Pharmaceuticals, and Mr. Brantley is having a back-and-forth with them concerning his part of the due diligence process that's described in
2	responses you didn't receive, okay? A. Okay.	2 3	Pharmaceuticals, and Mr. Brantley is having a back-and-forth with them concerning his part
2 3 4	responses you didn't receive, okay? A. Okay. MR. BUCHANAN: Can I have 1075, please. BY MR. BUCHANAN:	2 3 4	Pharmaceuticals, and Mr. Brantley is having a back-and-forth with them concerning his part of the due diligence process that's described in your revamped SOPs, correct? A. Yes.
2 3 4 5	responses you didn't receive, okay? A. Okay. MR. BUCHANAN: Can I have 1075, please. BY MR. BUCHANAN:	2 3 4 5	Pharmaceuticals, and Mr. Brantley is having a back-and-forth with them concerning his part of the due diligence process that's described in your revamped SOPs, correct? A. Yes. Q. Part of what you implemented in
2 3 4 5 6	responses you didn't receive, okay? A. Okay. MR. BUCHANAN: Can I have 1075, please. BY MR. BUCHANAN: Q. Who is Preferred Pharmaceuticals? A. I don't recall.	2 3 4 5 6 7	Pharmaceuticals, and Mr. Brantley is having a back-and-forth with them concerning his part of the due diligence process that's described in your revamped SOPs, correct? A. Yes. Q. Part of what you implemented in late 2013, correct?
2 3 4 5 6 7	responses you didn't receive, okay? A. Okay. MR. BUCHANAN: Can I have 1075, please. BY MR. BUCHANAN: Q. Who is Preferred Pharmaceuticals? A. I don't recall. Q. Does the name ring a bell to you?	2 3 4 5 6 7 8	Pharmaceuticals, and Mr. Brantley is having a back-and-forth with them concerning his part of the due diligence process that's described in your revamped SOPs, correct? A. Yes. Q. Part of what you implemented in late 2013, correct? MS. VANNI: Object to form.
2 3 4 5 6 7 8	responses you didn't receive, okay? A. Okay. MR. BUCHANAN: Can I have 1075, please. BY MR. BUCHANAN: Q. Who is Preferred Pharmaceuticals? A. I don't recall. Q. Does the name ring a bell to you? A. No, it does not.	2 3 4 5 6 7 8	Pharmaceuticals, and Mr. Brantley is having a back-and-forth with them concerning his part of the due diligence process that's described in your revamped SOPs, correct? A. Yes. Q. Part of what you implemented in late 2013, correct? MS. VANNI: Object to form. THE WITNESS: I'm sorry? I'm
2 3 4 5 6 7 8	responses you didn't receive, okay? A. Okay. MR. BUCHANAN: Can I have 1075, please. BY MR. BUCHANAN: Q. Who is Preferred Pharmaceuticals? A. I don't recall. Q. Does the name ring a bell to you?	2 3 4 5 6 7 8	Pharmaceuticals, and Mr. Brantley is having a back-and-forth with them concerning his part of the due diligence process that's described in your revamped SOPs, correct? A. Yes. Q. Part of what you implemented in late 2013, correct? MS. VANNI: Object to form. THE WITNESS: I'm sorry? I'm sorry, I was reading.
2 3 4 5 6 7 8 9 10	responses you didn't receive, okay? A. Okay. MR. BUCHANAN: Can I have 1075, please. BY MR. BUCHANAN: Q. Who is Preferred Pharmaceuticals? A. I don't recall. Q. Does the name ring a bell to you? A. No, it does not. Q. Okay. Let's kind of reorient ourselves.	2 3 4 5 6 7 8 9 10	Pharmaceuticals, and Mr. Brantley is having a back-and-forth with them concerning his part of the due diligence process that's described in your revamped SOPs, correct? A. Yes. Q. Part of what you implemented in late 2013, correct? MS. VANNI: Object to form. THE WITNESS: I'm sorry? I'm sorry, I was reading. BY MR. BUCHANAN:
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2 3 4 5 6 7 8 9 10 11 12 13 14 15	responses you didn't receive, okay? A. Okay. MR. BUCHANAN: Can I have 1075, please. BY MR. BUCHANAN: Q. Who is Preferred Pharmaceuticals? A. I don't recall. Q. Does the name ring a bell to you? A. No, it does not. Q. Okay. Let's kind of reorient ourselves. In 2013 after everything we've discussed, after the risk assessment you set forward, after some meetings with management, after procuring some resources and getting	2 3 4 5 6 7 8 9 10 11 12 13 14 15	Pharmaceuticals, and Mr. Brantley is having a back-and-forth with them concerning his part of the due diligence process that's described in your revamped SOPs, correct? A. Yes. Q. Part of what you implemented in late 2013, correct? MS. VANNI: Object to form. THE WITNESS: I'm sorry? I'm sorry, I was reading. BY MR. BUCHANAN: Q. You know what, fair. So in late 2013 you revamped your SOMS process, correct? MS. VANNI: Form.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	responses you didn't receive, okay? A. Okay. MR. BUCHANAN: Can I have 1075, please. BY MR. BUCHANAN: Q. Who is Preferred Pharmaceuticals? A. I don't recall. Q. Does the name ring a bell to you? A. No, it does not. Q. Okay. Let's kind of reorient ourselves. In 2013 after everything we've discussed, after the risk assessment you set forward, after some meetings with management, after procuring some resources and getting consent from others, you sent a letter out to	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Pharmaceuticals, and Mr. Brantley is having a back-and-forth with them concerning his part of the due diligence process that's described in your revamped SOPs, correct? A. Yes. Q. Part of what you implemented in late 2013, correct? MS. VANNI: Object to form. THE WITNESS: I'm sorry? I'm sorry, I was reading. BY MR. BUCHANAN: Q. You know what, fair. So in late 2013 you revamped your SOMS process, correct? MS. VANNI: Form. THE WITNESS: We made upgrades to
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	responses you didn't receive, okay? A. Okay. MR. BUCHANAN: Can I have 1075, please. BY MR. BUCHANAN: Q. Who is Preferred Pharmaceuticals? A. I don't recall. Q. Does the name ring a bell to you? A. No, it does not. Q. Okay. Let's kind of reorient ourselves. In 2013 after everything we've discussed, after the risk assessment you set forward, after some meetings with management, after procuring some resources and getting consent from others, you sent a letter out to customers, right? A. Yes. Q. Those customers included distributors, those customers included some end	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Pharmaceuticals, and Mr. Brantley is having a back-and-forth with them concerning his part of the due diligence process that's described in your revamped SOPs, correct? A. Yes. Q. Part of what you implemented in late 2013, correct? MS. VANNI: Object to form. THE WITNESS: I'm sorry? I'm sorry, I was reading. BY MR. BUCHANAN: Q. You know what, fair. So in late 2013 you revamped your SOMS process, correct? MS. VANNI: Form. THE WITNESS: We made upgrades to it starting BY MR. BUCHANAN: Q. Letters went out, correct? A. Letters went out then, yes.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	responses you didn't receive, okay? A. Okay. MR. BUCHANAN: Can I have 1075, please. BY MR. BUCHANAN: Q. Who is Preferred Pharmaceuticals? A. I don't recall. Q. Does the name ring a bell to you? A. No, it does not. Q. Okay. Let's kind of reorient ourselves. In 2013 after everything we've discussed, after the risk assessment you set forward, after some meetings with management, after procuring some resources and getting consent from others, you sent a letter out to customers, right? A. Yes. Q. Those customers included distributors, those customers included some end user pharmacies that were dealing direct with	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Pharmaceuticals, and Mr. Brantley is having a back-and-forth with them concerning his part of the due diligence process that's described in your revamped SOPs, correct? A. Yes. Q. Part of what you implemented in late 2013, correct? MS. VANNI: Object to form. THE WITNESS: I'm sorry? I'm sorry, I was reading. BY MR. BUCHANAN: Q. You know what, fair. So in late 2013 you revamped your SOMS process, correct? MS. VANNI: Form. THE WITNESS: We made upgrades to it starting BY MR. BUCHANAN: Q. Letters went out, correct? A. Letters went out then, yes. Q. Mr. Brantley conducted some due
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	responses you didn't receive, okay? A. Okay. MR. BUCHANAN: Can I have 1075, please. BY MR. BUCHANAN: Q. Who is Preferred Pharmaceuticals? A. I don't recall. Q. Does the name ring a bell to you? A. No, it does not. Q. Okay. Let's kind of reorient ourselves. In 2013 after everything we've discussed, after the risk assessment you set forward, after some meetings with management, after procuring some resources and getting consent from others, you sent a letter out to customers, right? A. Yes. Q. Those customers included distributors, those customers included some end user pharmacies that were dealing direct with the company, and you got responses from many of	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Pharmaceuticals, and Mr. Brantley is having a back-and-forth with them concerning his part of the due diligence process that's described in your revamped SOPs, correct? A. Yes. Q. Part of what you implemented in late 2013, correct? MS. VANNI: Object to form. THE WITNESS: I'm sorry? I'm sorry, I was reading. BY MR. BUCHANAN: Q. You know what, fair. So in late 2013 you revamped your SOMS process, correct? MS. VANNI: Form. THE WITNESS: We made upgrades to it starting BY MR. BUCHANAN: Q. Letters went out, correct? A. Letters went out then, yes. Q. Mr. Brantley conducted some due diligence visits, correct?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	responses you didn't receive, okay? A. Okay. MR. BUCHANAN: Can I have 1075, please. BY MR. BUCHANAN: Q. Who is Preferred Pharmaceuticals? A. I don't recall. Q. Does the name ring a bell to you? A. No, it does not. Q. Okay. Let's kind of reorient ourselves. In 2013 after everything we've discussed, after the risk assessment you set forward, after some meetings with management, after procuring some resources and getting consent from others, you sent a letter out to customers, right? A. Yes. Q. Those customers included distributors, those customers included some end user pharmacies that were dealing direct with	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Pharmaceuticals, and Mr. Brantley is having a back-and-forth with them concerning his part of the due diligence process that's described in your revamped SOPs, correct? A. Yes. Q. Part of what you implemented in late 2013, correct? MS. VANNI: Object to form. THE WITNESS: I'm sorry? I'm sorry, I was reading. BY MR. BUCHANAN: Q. You know what, fair. So in late 2013 you revamped your SOMS process, correct? MS. VANNI: Form. THE WITNESS: We made upgrades to it starting BY MR. BUCHANAN: Q. Letters went out, correct? A. Letters went out then, yes. Q. Mr. Brantley conducted some due

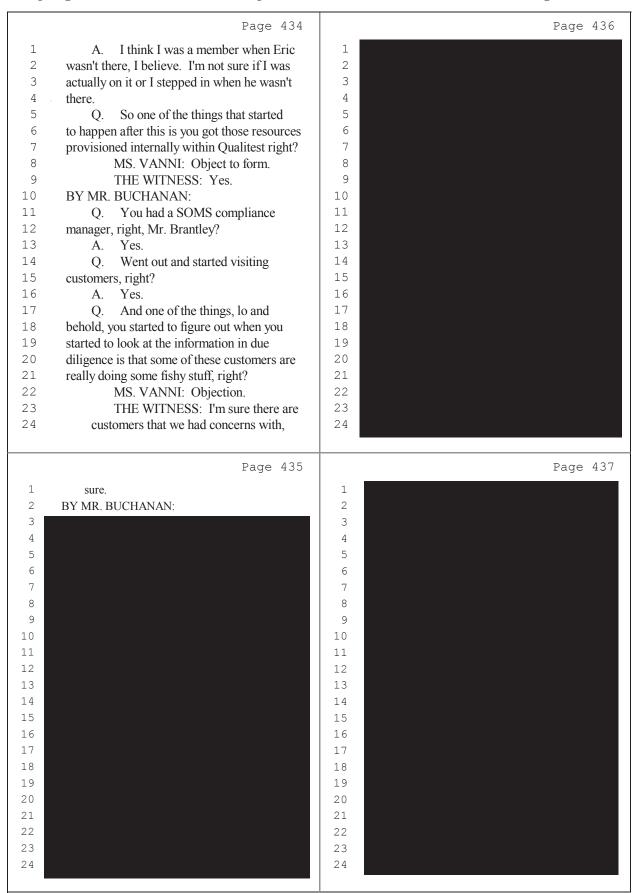


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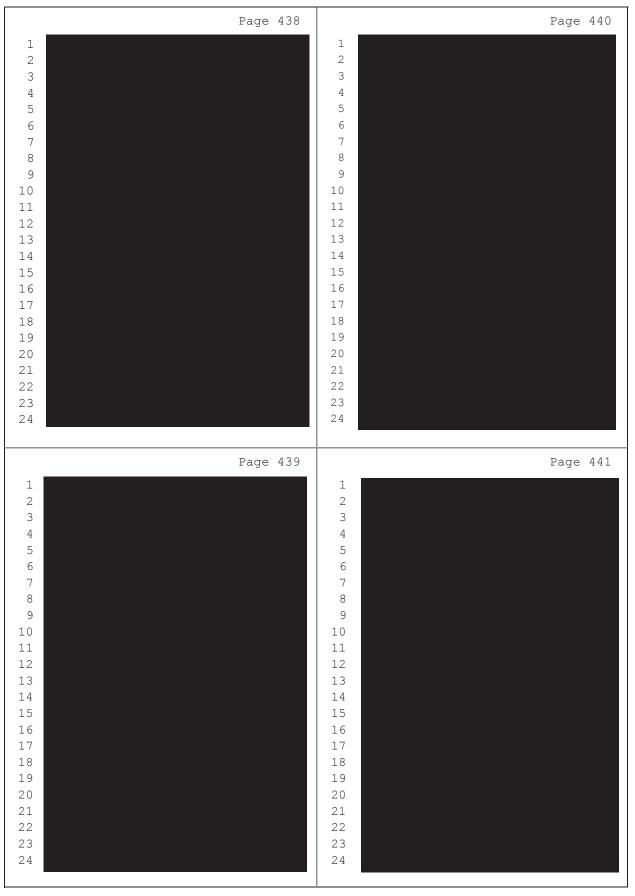


108 (Pages 426 to 429)

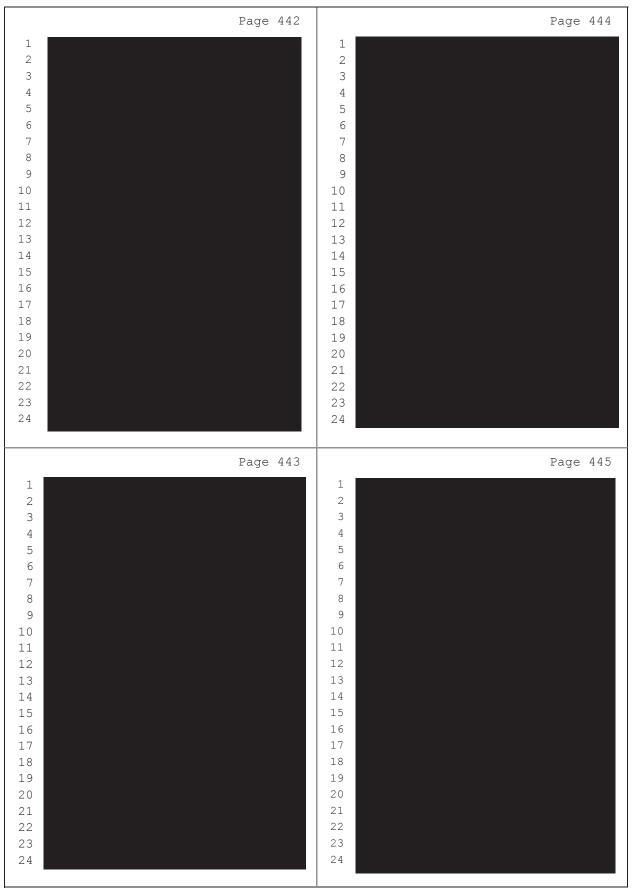
1 2 3 4 5 6	Pharmaceuticals for this is about, what, a year after, this is a year after your first	1	Page 432 BY MR. BUCHANAN:
2 3 4 5 6	year after, this is a year after your first		DI MIN, DUCHAMAN,
3 4 5 6		2	O Wa sould agree malem that from
4 . 5 6	lattan recent out might?	3	Q. We could agree, ma'am, that from the perspective of maintaining a closed system
5 6	letter went out, right? A. Uh-huh.	4	and having effective controls against diversion,
6			•
	Q. So a year after your first letter	5	it's not appropriate to sell drug to people that
/	goes out, you're still going back and forth with	6	don't have suspicious order monitoring in place,
	Preferred Pharma about whether they've got	7	right?
8	programs in place, right?	8	MS. VANNI: Object to form.
9	MS. VANNI: Object to form.	9	THE WITNESS: To have controls in
10	THE WITNESS: Well, keep in mind	10	place to make sure it doesn't go out the
11	too when you send out a letter	11	door
12	BY MR. BUCHANAN:	12	BY MR. BUCHANAN:
13	Q. Is that correct?	13	Q. Right.
14	A you don't know I don't know	14	A to illegitimate channels.
15	how long this went on.	15	Q. And what you were asking for were
16	Q. Well, I'm sorry. This is	16	their SOM programs, correct?
17	A. I mean, this is 2014, but I don't	17	A. Yes.
18	know what happened from the time of the letter	18	Q. That's what you asked for as part
19	to this.	19	of your due diligence information in October of
20	Q. October 21, 2014	20	2013, right?
21	A. Correct.	21	A. Correct.
22	Q correct, that's your last	22	Q. And if the company was shipping
23	e-mail? You're still not satisfied that they've	23	drug to people who didn't have programs in
24	got programs in place to keep this closed	24	place, that would be improper, right?
	Page 431		Page 433
1	system, right?	1	MS. VANNI: Objection.
2	A. I mean, you're making the	2	MR. LEEDER: Objection.
3	assumption that they were a customer when the	3	THE WITNESS: Depending on what
4	letter originally went out too. I don't even	4	else they had in place.
5	know that.	5	BY MR. BUCHANAN:
6	Q. That's a discernable fact, and we	6	Q. If they didn't have programs in
7	don't have time to root through the documents	7	place to ensure the effective control against
8	with you today, but that can be determined.	8	diversion, it would be improper for you to be
9	A. Right.	9	selling to them, right?
10	Q. I'll represent to you I I	10	MS. VANNI: Objection.
11	won't make a representation. I'll do that at	11	THE WITNESS: If it's they
12	another time.	12	don't have to have something they call
13	But this is a year after your	13	SOMS, so they have to have appropriate
14	letter went out, right?	14	controls, yes.
15	A. Yes. And it's an ongoing thing,	15	BY MR. BUCHANAN:
16	and the letter might not have gone to the right	16	Q. Okay. I mean, they certainly
17	person in the company to start with either. It	17	can't well, let's take a look at some.
18	might have had to have gone through, you know,	18	Did you form a SOMS advisory team
19	several people once it got there, so a lot of	19	in late 2013, early 2014?
20	logistics in the process.	20	A. Yes, we did.
21	MR. BUCHANAN: Can I have 1145.	21	Q. Mr. Brantley was a member of
22	(Document marked for	22	that?
23	identification as Par-Norton Deposition	23	A. Yes, he was.
24	Exhibit No. 22.)	24	Q. Were you a member of that?
	Damon 110. 22.J	24	v. Were you a member of that!



110 (Pages 434 to 437)

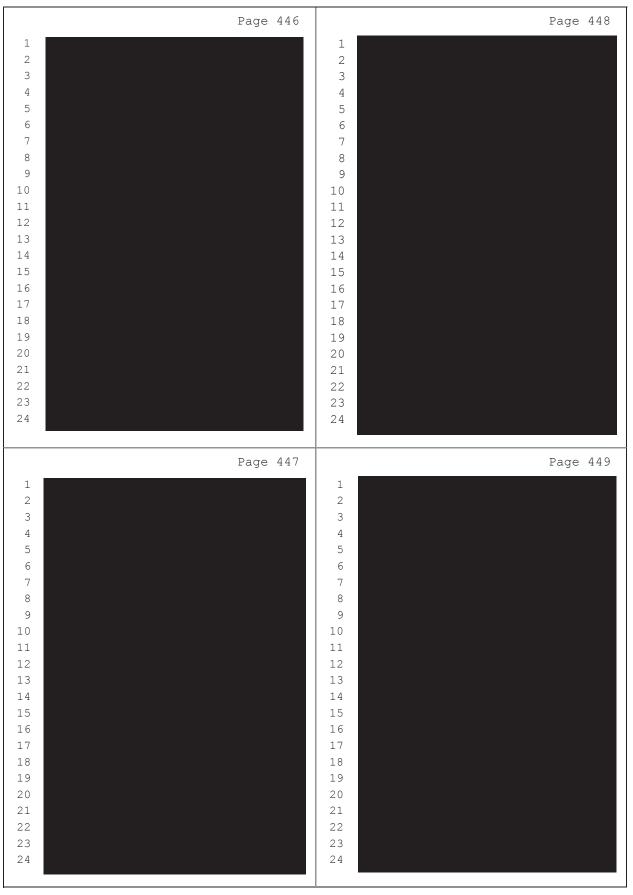


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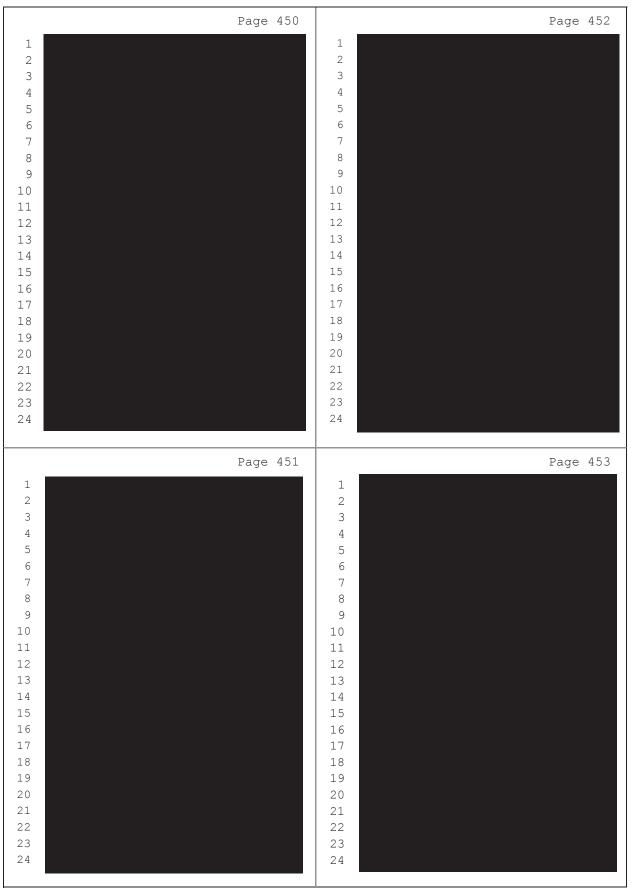


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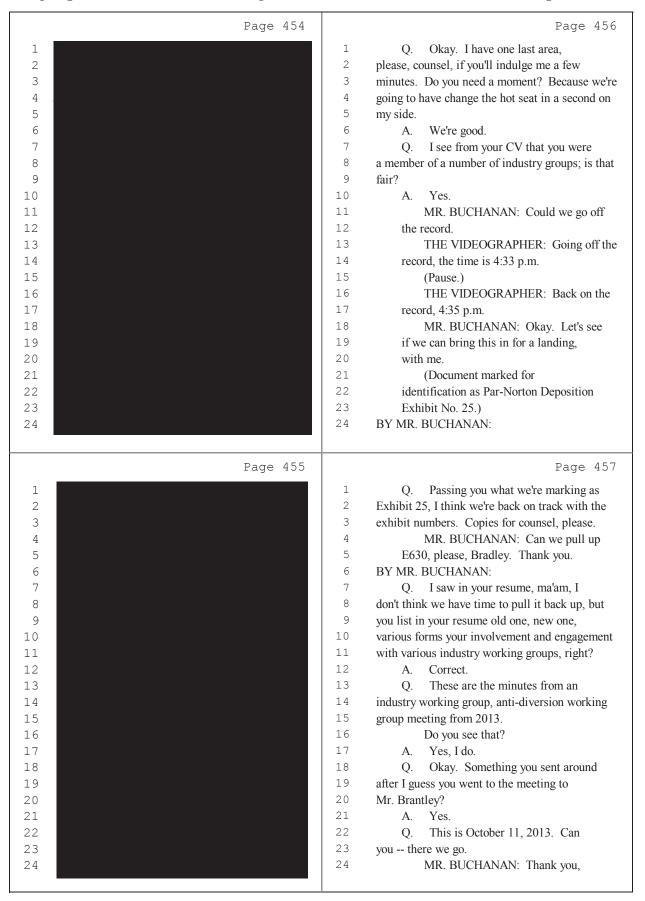


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114 (Pages 450 to 453)

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115 (Pages 454 to 457)

	Page 458		Page 460
1	Bradley.	1	BY MR. BUCHANAN:
2	BY MR. BUCHANAN:	2	Q. Okay. And so Anti-Diversion
3	Q. And then you've got your DEA	3	Industry Working Group, that was a group of
4	compliance trip report, right?	4	industry participants that came together from
5	A. Yes.	5	time to time, right?
6	Q. Did you put this together?	6	A. Not we really didn't meet a
7	A. Yes, I did.	7	lot. It was more for one purpose.
8	Q. And it accurately reflected what	8	Q. Okay. And this notes it's the
9	happened, as best you were able to determine?	9	second meeting of the group, correct?
10	A. Yes.	10	A. Yes.
11	Q. Okay. And so this is a meeting	11	Q. Okay. And then you had some
12	of the Anti-Diversion Industry Working Group	12	folks from Quarles & Brady, those are lawyers?
13	held in Chicago, right?	13	A. Yes.
14	A. Correct.	14	Q. Okay. So you had lawyers, you
15	Q. And you've got you've got some	15	had distributors, you had manufacturers all kind
16		16	of in this group together, right?
17	folks from manufacturers, Mallinckrodt, right? A. Yes.	17	MS. VANNI: Object to form.
18		18	THE WITNESS: Correct.
	•	19	
19	AmerisourceBergen, right?		BY MR. BUCHANAN:
20	A. Yes.	20	Q. All right. And then maybe we'll
21	Q. McKesson dialing in, right?	21	have time to call out some of these. Carmen is
22	A. Yes.	22	a person who spoke that day. You see at the
23	Q. AmerisourceBergen there in	23	bottom of the first page, Carmen Catizone?
24	person?	24	A. Yes.
	Page 459		Page 461
			Tage 401
1		1	
1 2	MR. SCHACK: Objection. What are	1 2	Q. And she gave some background on
2	MR. SCHACK: Objection. What are you looking at? Sorry, I don't have it.	2	Q. And she gave some background on NAPB, right?
2	MR. SCHACK: Objection. What are you looking at? Sorry, I don't have it. MR. BUCHANAN: Can we get the	2 3	Q. And she gave some background on NAPB, right? A. He. He was the executive
2 3 4	MR. SCHACK: Objection. What are you looking at? Sorry, I don't have it. MR. BUCHANAN: Can we get the 630.2.	2 3 4	Q. And she gave some background on NAPB, right? A. He. He was the executive director of NAPB.
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2 3 4 5 6 7	MR. SCHACK: Objection. What are you looking at? Sorry, I don't have it. MR. BUCHANAN: Can we get the 630.2. MS. KOSKI: It took our screen away too. MR. SCHACK: Yeah, I can't see	2 3 4 5 6 7	Q. And she gave some background on NAPB, right? A. He. He was the executive director of NAPB. Q. NAPB is what? A. National Association of Boards of Pharmacy.
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2 3 4 5 6 7 8	MR. SCHACK: Objection. What are you looking at? Sorry, I don't have it. MR. BUCHANAN: Can we get the 630.2. MS. KOSKI: It took our screen away too. MR. SCHACK: Yeah, I can't see the MR. BUCHANAN: Just turn the one	2 3 4 5 6 7 8	Q. And she gave some background on NAPB, right? A. He. He was the executive director of NAPB. Q. NAPB is what? A. National Association of Boards of Pharmacy. Q. Okay. And Carmen is providing information on wholesalers or secondary
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2 3 4 5 6 7 8 9 10 11	MR. SCHACK: Objection. What are you looking at? Sorry, I don't have it. MR. BUCHANAN: Can we get the 630.2. MS. KOSKI: It took our screen away too. MR. SCHACK: Yeah, I can't see the MR. BUCHANAN: Just turn the one right there. Okay. I can't solve for that, I'm sorry. 630.2. BY MR. BUCHANAN:	2 3 4 5 6 7 8 9 10 11 12	Q. And she gave some background on NAPB, right? A. He. He was the executive director of NAPB. Q. NAPB is what? A. National Association of Boards of Pharmacy. Q. Okay. And Carmen is providing information on wholesalers or secondary wholesalers being a diversion risk, correct? A. Second that's what he's saying, yes.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MR. SCHACK: Objection. What are you looking at? Sorry, I don't have it. MR. BUCHANAN: Can we get the 630.2. MS. KOSKI: It took our screen away too. MR. SCHACK: Yeah, I can't see the MR. BUCHANAN: Just turn the one right there. Okay. I can't solve for that, I'm sorry. 630.2. BY MR. BUCHANAN: Q. At the top we have a list of attendees at the meeting, and you were the Qualitest attendee, correct? A. Yes, I was. MR. BUCHANAN: Does everybody have a way to get an angle on this right now? If someone needs to stand up over my shoulder, they're welcome to do that. MR. SCHACK: What exhibit number,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. And she gave some background on NAPB, right? A. He. He was the executive director of NAPB. Q. NAPB is what? A. National Association of Boards of Pharmacy. Q. Okay. And Carmen is providing information on wholesalers or secondary wholesalers being a diversion risk, correct? A. Second that's what he's saying, yes. Q. I'm sorry. It's the last paragraph. A. Yes, that's what he's saying. Q. First page. Okay. And then there's some member presentations that occur? A. Yes. Q. Right. And the members would be all these folks that are identified other than

Page 462 Page 464 you know, there's this IMS data with a heat map? 1 1 members, and you don't identify that person, is 2 2 that just some code of conduct or something when A. I did. It's not standard 3 you go to these meetings, you're not allowed to 3 information to get. It's extremely, extremely 4 4 costly, in the millions, from what I was told to say who said what? 5 MS. VANNI: Object to form. 5 get that information. So it wasn't something 6 THE WITNESS: No. that we wanted to do at that time. It gave us 7 BY MR. BUCHANAN: 7 some information, but DEA was presenting similar 8 Q. I don't know, you didn't? 8 things at conferences, so it wasn't something 9 9 A. No, it was just one of the team that we pursued. 10 members. I don't recall which one it was, but 10 Q. Okay. Well, I mean, you could 11 one of them presented IMS data. 11 drill down, right, using these heat maps? 12 MS. VANNI: Object to form. 12 Okay. Well, for the outside 13 13 presenter, you identify them by name and then THE WITNESS: I don't know if we 14 for the other people you attribute them as team 14 could in this case or not. The 15 15 presentation wasn't -- it wasn't -members, right? 16 MR. SCHACK: Object to form. 16 like, it wasn't -- they didn't spend a 17 17 long time on it. It was just here's THE WITNESS: No reason. 18 18 something out there. The whole purpose BY MR. BUCHANAN: 19 O. Okay. "Member Presentation 19 of the group was to try to do anything 20 20 (Based on IMS data). One of the team members that we could to help with the abuse and 21 has purchased the upgraded IMS subscription and 21 diversion, and so this was presented as 22 using the data IMS provides, presented a heat 22 a tool that one company had that -- just 23 23 to educate people that it was out there map of the US showing the top prescribers for 24 24 oxycodone and hydrocodone from 2010 - 2013," on the team. Page 463 Page 465 1 1 BY MR. BUCHANAN: right? 2 2 A. Yes. Q. All right. I mean, what they 3 And it showed the following 3 said you could see was you could see a map of the US showing the top prescribers for oxycodone 4 states in this heat map. and hydrocodone, right? That's what it showed, 5 5 You see this? 6 A. I do. 6 the heat map? 7 7 Q. Yeah, and you identify several --A. I don't know if it drilled down 8 for hydrocodone you've got Ohio, California, 8 to the actual names of prescribers or anything 9 Texas, you see Florida in there, other states in 9 like that. 10 10 the mix, right? Well, you were sufficiently 11 11 A. Yes. impressed, you say --12 Okay. You've got them also for 12 A. I was. 13 13 the seven and a half milligrams hydrocodone, MS. VANNI: Object to form. 14 also for 10 milligrams, correct? 14 THE WITNESS: I was. It was 15 15 Yes. interesting information. 16 16 All right. And so these are BY MR. BUCHANAN: O. 17 17 Q. Not only interesting, you said we states that are popping up on this heat map, 18 18 need to get it? right? 19 19 A. I wanted to get it if it was MS. VANNI: Object to form. THE WITNESS: That's what it was 20 reasonable and was something that we could use 20 21 21 on a regular basis, yeah. showing, yes. 22 BY MR. BUCHANAN: 22 Well, in the context of billions 23 23 Q. Okay. Did you go back to the and billions of pills that you're selling and company after you went to this and said, hey, 24 24 the tens of thousands of people that are

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Page 466
                                                                                                       Page 468
                                                              1
 1
       overdosing each year, I mean, how many millions
                                                                    get information that could be relevant to you,
 2
                                                              2
       of dollars is too much to spend to acquire data
                                                                    in your view?
 3
       to help prevent diversion?
                                                              3
                                                                             MS. VANNI: Object to form.
 4
            A. I don't think --
                                                              4
                                                                    BY MR. BUCHANAN:
 5
                 MS. VANNI: Objection, form.
                                                              5
                                                                         Q. As part of your role and
                                                              6
 6
                 THE WITNESS: I don't think that
                                                                    function?
 7
            this data would have been -- it was
                                                              7
                                                                         A.
                                                                             I don't know if it was really
            informative more than it was helpful in
                                                              8
 8
                                                                    anything new compared to what DEA was putting
 9
                                                              9
                                                                    out there. Again, at that point I hadn't
            preventing diversion.
10
       BY MR. BUCHANAN:
                                                            10
                                                                    attended it, so it's probably more helpful to a
11
                 What you wrote here was that "we
                                                            11
                                                                    wholesaler, HDMA.
       need to obtain this data"?
                                                            12
12
                                                                              Okay. I was more generalizing.
                                                            13
13
            A. That's what I wanted to do, yes.
                                                                    I mean, this particular working group, I mean,
                                                            14
14
            Q.
                This was as of --
                                                                    getting together with others in the industry,
15
                                                            15
                                                                    collaborating, understanding what's happening,
            A.
                  Because I always want to improve
                                                                    data sources that might be available, that was
                                                            16
16
       upon our compliance and the tools that are
                                                            17
17
                                                                    information that you brought back to incorporate
       available to us and to what we're doing.
18
                                                            18
                 Okay. Do you remember how much
                                                                    in your practice?
19
       it was? I would like to know how much --
                                                            19
                                                                             MS. VANNI: Object to form.
20
                                                            20
            A. I don't remember.
                                                                             THE WITNESS: It was information
21
            Q. -- was too much for Qualitest?
                                                            21
                                                                         that I brought back and made the team
22
                I don't remember, to be honest.
                                                            22
                                                                         knowledgeable of, and, ultimately, the
23
                                                            23
                 MS. VANNI: Objection.
                                                                         goal and the end result of this team was
                                                            24
24
                 THE WITNESS: I don't remember.
                                                                         the red flags video that NABP still
                                          Page 467
                                                                                                       Page 469
                                                              1
 1
        BY MR. BUCHANAN:
                                                                         today has on their website.
                                                              2
 2
             Q. Okay. And then there's some
                                                                    BY MR. BUCHANAN:
 3
        discussion on other key topics, how to best
                                                              3
                                                                         Q. The red flags video being signs
                                                              4
                                                                    for pharmacies, signs for pharmacists, et
 4
        assure success of the team partnering with the
 5
                                                              5
                                                                    cetera?
        DEA.
                                                              6
 6
                  Do you see that? It's the first
                                                                             Signs for -- yes, it was
 7
                                                              7
        bullet under "Other Key Topics Discussed."
                                                                    educational for pharmacists to show them some of
 8
             A. Yes, how best to assure the
                                                              8
                                                                    the things to look for that we thought would be
                                                              9
 9
        success in partnering to fight drug diversion.
                                                                    helpful.
                                                            10
10
             O. Right. And so the "team felt we
                                                                         Q. How about a video for any of your
                                                            11
11
        should evaluate the HDMA's actions."
                                                                    customers, your distributors, one that would
12
                 Do you see that?
                                                            12
                                                                    show them, hey, these are what problematic
                                                            13
                                                                    pharmacies look like and lines out the door and
13
                 Yes, I do.
14
                  Okay. And who is the HDMA?
                                                            14
                                                                    red flags and other things that would help them?
             O.
                                                            15
                                                                             MS. VANNI: Objection.
15
                  Healthcare Distributor Management
                                                            16
16
        Association.
                                                                            THE WITNESS: They were, as part
17
                                                            17
                                                                        of the -- you know, as part of NABP,
             O.
                  And were those meetings that you
18
                                                            18
                                                                         they would have been seeing that, that
        also attended?
19
                                                            19
                                                                         video anyway.
                  They had a conference once a
20
        year. I attended one, but at this point I had
                                                            20
                                                                    BY MR. BUCHANAN:
21
                                                            21
                                                                        Q. Like FW Kerr would have been
        not -- I have attended one in the past, but at
22
        this point I had never attended any.
                                                            22
                                                                    seeing that?
                                                            23
23
             Q. Okay. And so you'd go to these
                                                                             MS. VANNI: Objection.
                                                            24
24
        meetings and as part of these meetings, you'd
                                                                             THE WITNESS: They could have.
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	Page 470		Page 472
1	It's public knowledge. It's publicly on	1	kind of thing, not really a
2	the website today.	2	collaboration, not really a
3	MR. BUCHANAN: Okay. Can I have	3	collaboration. There wasn't there
4	1153.	4	was no direct outcome of this meeting,
5	(Document marked for	5	like the anti-diversion group meetings,
6	identification as Par-Norton Deposition	6	and this was actual this group was
7	Exhibit No. 26.)	7	actually started by Gerry McAleer, the
8	BY MR. BUCHANAN:	8	local special agent in charge of the DEA
9	Q. These are minutes of another DEA	9	office in Newark, New Jersey.
10	compliance trip report. This is from the same	10	BY MR. BUCHANAN:
11	window of time, fall 2013?	11	Q. Okay. Is he in attendance at
12	A. Mm-hmm.	12	this?
13	Q. I noticed, just from looking	13	A. I don't think he's in attendance
14	through your file, ma'am, that in this 2013	14	at this one. He was in attendance and spoke at
15	period, you're going to outside industry	15	the first one
16		16	
17	functions and sending and memorializing them	17	Q. Okay. So what A and he was invited to other
18	in trip reports and sending them out to your team when you get back; is that fair?	18	
18 19		19	meetings. Other members of DEA were invited to
	A. Something that I've always done,	20	meetings afterwards.
20	not just in 2013.		Q. Well, we could agree he's not at
21	Q. So this is of the New Jersey	21	this one, correct?
22	Pharmaceutical Industry Group meeting from	22	A. I wouldn't know without reading
23	November of 2013, correct?	23	the whole thing, but I don't think so.
24	A. Yes.	24	Q. Okay. Well, certainly, with
	Dana 471		
	Page 471		Page 473
1	_	1	
1 2	Q. Hosted at Novartis, correct?	1 2	regard to the additional attendees, do you see
2	Q. Hosted at Novartis, correct?A. Yes, this particular one was.	2	regard to the additional attendees, do you see any notation of a DEA attendee?
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	Page 474		Page 476
1	Q. Sure.	1	a standard turnaround might be eight to
2	Next paragraph, "The goal of the	2	ten weeks, and in one instance that I
3	NJPIG is to increase compliance with DEA	3	can recall it was taking DEA upwards of
4	requirements through the shared knowledge and	4	24 weeks to respond to a quota letter,
5	experience of the group members."	5	which, as you can see from the comment
6	Do you see that?	6	there, it had an impact on drug supply
7	A. Yes.	7	and created drug shortages.
8	Q. Okay. And was that one of was	8	BY MR. BUCHANAN:
9	that something that was happening at these	9	Q. Okay. And strategies for dealing
10	meetings; y'all were sharing your experiences	10	with them, right?
11	back and forth?	11	A. Not really strategies. I mean
12	A. Yes. I mean, there were some	12	MS. VANNI: Objection.
13	members that were more senior, others were newer	13	THE WITNESS: there's
14	to DEA compliance. There was a fine line	14	nothing not much that companies can
15	because there's a lot of things that we couldn't	15	do. If DEA wants to take longer, they
16	speak about from confidentiality perspective,	16	take longer, you know.
17	because we were also competitors, but there was	17	BY MR. BUCHANAN:
18	information sharing to the extent that it could	18	Q. Let's then turn to 1153.4, also
19	be.	19	discussing SOM programs, right?
20	Q. Okay. Let's go to 1153.2. It	20	A. Yes.
21	talks about 2014 quota letters. Do you see	21	Q. And question being put out to
22	that?	22	everybody at the meeting, "Is anyone auditing
23	A. Yes.	23	customers?"
24	Q. And quota letters are the	24	MS. VANNI: Object to form.
1	Page 475		Page 477
1	manufacturers will send in a request for	1	THE WITNESS: Correct, because it
2	permission to make a certain quantity of	2	was something that
3	controlled substance?	3	BY MR. BUCHANAN:
4	A. Yes, it's based on sales data.	4	Q. So just let's pause on that.
5	It's based on IMS data, prescriptions written.	5	A. Okay.
6	DEA takes a lot of other factors into	6	Q. I mean, that's what it reflects,
7	consideration, meet with FDA, et cetera.	7	right, "Is anyone auditing customers?"
8	Q. And members here are expressing	8	A. Yes.
9	surprise to receive the quota letter for 2014.	9	Q. Okay. "Computerized statistical
10	Do you see that?	10	models?" Right?
11	A. Yes.	11	A. Yes.
12	Q. And some members said it was	12	Q. Okay. And so this was a vehicle,
13	because of the reason that GAO is reviewing last	13	this New Jersey Pharmaceutical Industry Group to
14	two years of quota issued by DEA, right?	14	exchange information about what people were
15	A. Yes, that's what it says.	15	doing on auditing, what people were doing on
16	Q. Okay. Was one of the things that	16	SOMS, what people were doing with statistical
17	industry would discuss at these meetings what	17	models, right?
18	participants were doing with regard to their	18	A. To a certain extent. So you
1 1 0	quota letters?	19	might get an answer to this question like a yes
19	MD LEEDED, Ohiostica	20	or no, but you wouldn't necessarily get a lot of
20	MR. LEEDER: Objection.		
20 21	THE WITNESS: They would never	21	detail because that was confidential to the
20 21 22	THE WITNESS: They would never discuss quota amounts. They would talk	22	company.
20 21	THE WITNESS: They would never		

	Page 478		Page 480
1	name as reflected in Rohit's memo. Teva is	1	industry association meetings concerning SOMS
2	replying that they do customer audits, sending	2	and anti-diversion efforts?
3	regular questionnaires and how they're going	3	A. Those are the only two that I can
4	about it, right?	4	recall.
5	A. Yes.	5	Q. Okay.
6	Q. The representative for Watson	6	A. Other than conferences, you know,
7	said how they do the risk assessment based on	7	industry conferences.
8	sales history and quotas, correct?	8	Q. My last document for you today.
9	A. Yes, that's what it says.	9	MR. BUCHANAN: Do I have a few
10	Q. Customers have to fill out	10	more minutes. How much time have I
11	questionnaires, and they described their process	11	used?
12	at the meeting, right?	12	THE VIDEOGRAPHER: Six hours, six
13	A. Looks that way, yes.	13	minutes.
14	Q. AmerisourceBergen is a	14	MR. BUCHANAN: Okay.
15	distributor and they're sharing what they're	15	(Document marked for
16	doing at that point in time, right?	16	identification as Par-Norton Deposition
17	MR. SCHACK: Objection.	17	Exhibit No. 27.)
18	THE WITNESS: It does talk to	18	BY MR. BUCHANAN:
19	AmerisourceBergen, yes.	19	Q. Passing you, ma'am, Exhibit 27.
20	BY MR. BUCHANAN:	20	Exhibit 27 is a PowerPoint you put together in
21	Q. Okay. It further notes there was	21	2014. I guess this is shortly before you move
22 23	a "general discussion included an important	22	on to HD Smith, right? A. Yes.
23	point for companies involved in SOMS program should document their thought process," right?	24	A. Yes. Q. Okay. Attached you'll find
24	should document their thought process, fight?	4	Q. Okay. Attached you'll filld
	Down 470		Daga 401
	Page 479		Page 481
1	A. Yes, that's what it says.	1	presentation from the recent Buzzeo PDMA
2	Q. And these are just general	2	seminar.
3	discussions and suggestions from company to	3	Do you see that?
4	company about how to manage their SOMS program,	4	A. Yes.
5	right?	5	Q. Okay. Is this a presentation you
6	MS. VANNI: Object to form.	6	prepared?
7	THE WITNESS: I don't know	7	A. Not this entire thing, no.Q. Oh, fair enough. I mean,
8	exactly what it means. I would assume docu you know, document your due	8 9	
10	diligence.	10	there's this is a compilation of presentations from that day, but this looks like
11	BY MR. BUCHANAN:	11	it's the seminar book, right?
12	Q. Right.	12	A. Yes.
13	Additionally, general discussion	13	Q. Okay. Let me take you to where I
14	included an important point, right?	14	think yours is and you can confirm that for us.
15	You see that?	15	It's 1059.290.
16	A. Mm-hmm, yes, that's what it says.	16	A. Yes, that's correct.
17	Q. For companies involved in SOMS	17	Q. Okay. And so this is you
18	programs to document their thought process.	18	presenting at the consultant the conference
19	Did I read that correctly?	19	for one of the consultants who came and did the
20	A. Yes, that's what it says.	20	inspection at your facility earlier, right?
21	Q. Apart from your attendance at	21	A. This particular consultant has a
22	industry meetings, the New Jersey Pharmaceutical	22	regular conference. A lot of times they have
23	Industry Group and the anti-diversion working	23	DEA actually attend their conference. In this
24	group, did you attend other groups like this	24	particular instance, they did not, and I was
			1

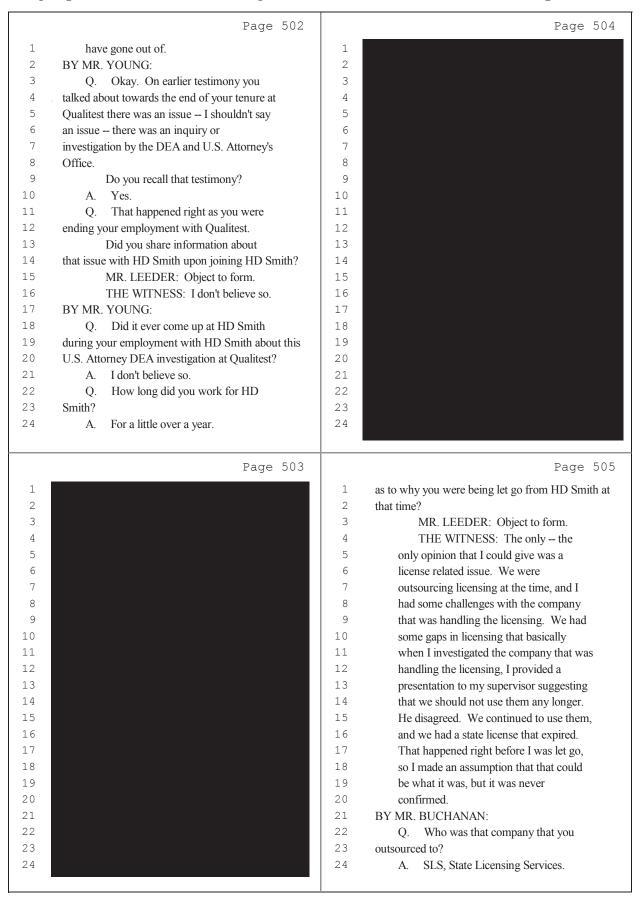
	Page 482		Page 484
1	asked to speak at it.	1	Q. Reducing Risk.
2	Q. And what you wrote here is	2	Protecting Reputation, that's
3	"Developing a robust suspicious order monitoring	3	another reason to do it, I guess, right?
4	program," right?	4	A. Yes.
5	A. Yes.	5	MS. VANNI: Object to form.
6	Q. And did you deliver this	6	THE WITNESS: Basically, you
7	presentation?	7	don't want to have any DEA violations.
8	A. I did.	8	BY MR. BUCHANAN:
9	Q. And this was a presentation to	9	Q. "Preventing Violations"?
10	manufacturers, wholesalers, distributors, people	10	A. Mm-hmm.
11	in the industry concerning controlled	11	Q. "Guarding Your Company & Your
12	substances?	12	License," right?
13	A. A very small group of them, yes.	13	A. The wording with guarding was
14	Q. Okay. And where was it?	14	talking about building in layers of security
15	A. I believe it was in Florida.	15	into your program.
16	Q. Okay.	16	Q. And I mean how about, you know,
17	A. I'm not positive. Actually, it	17	making sure that we don't fuel the second
18	might have been in Maryland.	18	epidemic anymore; that would be a good reason to
19	Q. Okay. At page 291, suspicious	19	do it, right?
20	order monitoring, you again note "DEA's Closed	20	MS. VANNI: Objection.
21	Loop Distribution System," right?	21	THE WITNESS: Not the case, but,
22	A. Yes.	22	yes.
23	Q. It's got to be a "Legitimate	23	BY MR. BUCHANAN:
24	Medical Need, by an Individual Practitioner	24	Q. Not the case, that's not a good
2 1	victical reca, by an individual reactioner		Q. Frot the case, that's not a good
	Page 483		Page 485
		1	
1	Acting in the Usual Course of His or Her	1	reason?
1 2	Acting in the Usual Course of His or Her Professional Practice "right?	1 2	reason? MS_VANNI: Objection
2	Professional Practice," right?	2	MS. VANNI: Objection.
2	Professional Practice," right? A. Yes.	2 3	MS. VANNI: Objection. THE WITNESS: No, it's not the
2 3 4	Professional Practice," right? A. Yes. Q. You also note "Being a Good	2 3 4	MS. VANNI: Objection. THE WITNESS: No, it's not the case as to what the company was doing.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Professional Practice," right? A. Yes. Q. You also note "Being a Good Corporate Citizen," right? A. Yes, because that's how I look at things, yes. Q. Doing everything in our power to prevent abuse and diversion, right? MS. VANNI: Objection. THE WITNESS: Always looking to improve and do more is what my goal is personally. BY MR. BUCHANAN: Q. And what the company's statement about its corporate responsibility through your letter in October of 2018 was we have to do everything we can, right? MS. VANNI: Objection. THE WITNESS: I believe so. BY MR. BUCHANAN:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MS. VANNI: Objection. THE WITNESS: No, it's not the case as to what the company was doing. BY MR. BUCHANAN: Q. Okay. And then 1059.296, you talk about "Robust Data Analysis Tool," right? A. Yes. Q. One of the things you do is "Receive Regular Data Feeds," right? A. Yes. Q. Those data feeds should be the sales to direct customer, first one, right? A. Correct. Q. Next thing is to "Chargeback Data," right? A. Yes, that's what it says. Q. This is what you're teaching people, right? A. Yes. MS. VANNI: Object to form.

	Page 486		Page 488
1	A. To look at this, yes.	1	A. Right.
2	Q. To look at chargeback data so you	2	Q. And you've got the I guess the
3	can, what, one, know your customer, right?	3	cute cartoon, I don't know if that's Sherlock
4	A. Yes.	4	Holmes or someone there on the right?
5	Q. And their customer, right?	5	A. Look to your customer.
6	A. Correct.	6	Q. There you go.
7	Q. And their customer, right?	7	A. Look at your customer closely.
8	MS. VANNI: Object to form.	8	Q. Know your customer again, right?
9	THE WITNESS: That's what it	9	A. Yes.
10	says.	10	Q. And so, first, know your customer
11	BY MR. BUCHANAN:	11	by virtue of data feeds, that was your prior
12	Q. That's what you wrote.	12	slide, correct?
13	A. Know as much as you can based on	13	A. Correct.
14	the data that's available to you.	14	Q. Next, know your customer by
15	Q. It's what you wrote and what you	15	on-site visits, right?
16	presented, ma'am, correct?	16	
		17	•
17	A. Yes.		repetitive of things that DEA suggestions
18	Q. Chargeback data, to know your	18	that they were making.
19	customer and their customer and their customer,	19	Q. This is a presentation you're
20	correct?	20	making outside the company to those in industry,
21	A. Yes.	21	fair?
22	Q. "Dispensing Data," another	22	A. Yes.
23	category, right?	23	Q. And you thought these were
24	A. That's what I wrote, yes.	24	important points to highlight, fair?
1			
	() These are the information feeds	1	 A. To reiterate what I had heard DEA
	Q. These are the information feeds that the company should be taking in for	1 2	
2	that the company should be taking in for		say, yes.
2	that the company should be taking in for suspicious order monitoring system, correct?	2	say, yes. Q. And, really, we had seen those in
2 3 4	that the company should be taking in for suspicious order monitoring system, correct? MS. VANNI: Object to form.	2 3 4	say, yes. Q. And, really, we had seen those in your own writings well before the meeting in
2 3 4 5	that the company should be taking in for suspicious order monitoring system, correct? MS. VANNI: Object to form. THE WITNESS: These are	2 3	say, yes. Q. And, really, we had seen those in your own writings well before the meeting in March of 2013, correct?
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2 3 4 5 6 7 8	that the company should be taking in for suspicious order monitoring system, correct? MS. VANNI: Object to form. THE WITNESS: These are suggestions to companies for things that they can add to their suspicious order monitoring program.	2 3 4 5 6 7 8	say, yes. Q. And, really, we had seen those in your own writings well before the meeting in March of 2013, correct? A. Yes, the improvements that I wanted to make. Q. That's a yes answer, ma'am?
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2 3 4 5 6 7 8 9 10 11 12 13 14	that the company should be taking in for suspicious order monitoring system, correct? MS. VANNI: Object to form. THE WITNESS: These are suggestions to companies for things that they can add to their suspicious order monitoring program. BY MR. BUCHANAN: Q. And with regard to dispensing data, what you told people, look at national average or actual cleansed dispensing data, right? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14	say, yes. Q. And, really, we had seen those in your own writings well before the meeting in March of 2013, correct? A. Yes, the improvements that I wanted to make. Q. That's a yes answer, ma'am? A. Yes. Q. Those are the you knew that these were important components as part of a SOM process even before you sat down with the DEA in March of 2013, correct? A. Again
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	that the company should be taking in for suspicious order monitoring system, correct? MS. VANNI: Object to form. THE WITNESS: These are suggestions to companies for things that they can add to their suspicious order monitoring program. BY MR. BUCHANAN: Q. And with regard to dispensing data, what you told people, look at national average or actual cleansed dispensing data, right? A. Yes. Q. And use that to help set a standard for long-term levels, correct? A. That's what it says, yes. Q. Can we go to the next page.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	say, yes. Q. And, really, we had seen those in your own writings well before the meeting in March of 2013, correct? A. Yes, the improvements that I wanted to make. Q. That's a yes answer, ma'am? A. Yes. Q. Those are the – you knew that these were important components as part of a SOM process even before you sat down with the DEA in March of 2013, correct? A. Again – MS. VANNI: Object to form. THE WITNESS: – they aren't required, they aren't required by DEA. They are suggested improvements.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	that the company should be taking in for suspicious order monitoring system, correct? MS. VANNI: Object to form. THE WITNESS: These are suggestions to companies for things that they can add to their suspicious order monitoring program. BY MR. BUCHANAN: Q. And with regard to dispensing data, what you told people, look at national average or actual cleansed dispensing data, right? A. Yes. Q. And use that to help set a standard for long-term levels, correct? A. That's what it says, yes. Q. Can we go to the next page. Customer due diligence visits, right? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	say, yes. Q. And, really, we had seen those in your own writings well before the meeting in March of 2013, correct? A. Yes, the improvements that I wanted to make. Q. That's a yes answer, ma'am? A. Yes. Q. Those are the you knew that these were important components as part of a SOM process even before you sat down with the DEA in March of 2013, correct? A. Again MS. VANNI: Object to form. THE WITNESS: they aren't required, they aren't required by DEA. They are suggested improvements. MR. BUCHANAN: Move to strike. BY MR. BUCHANAN: Q. You knew they were important

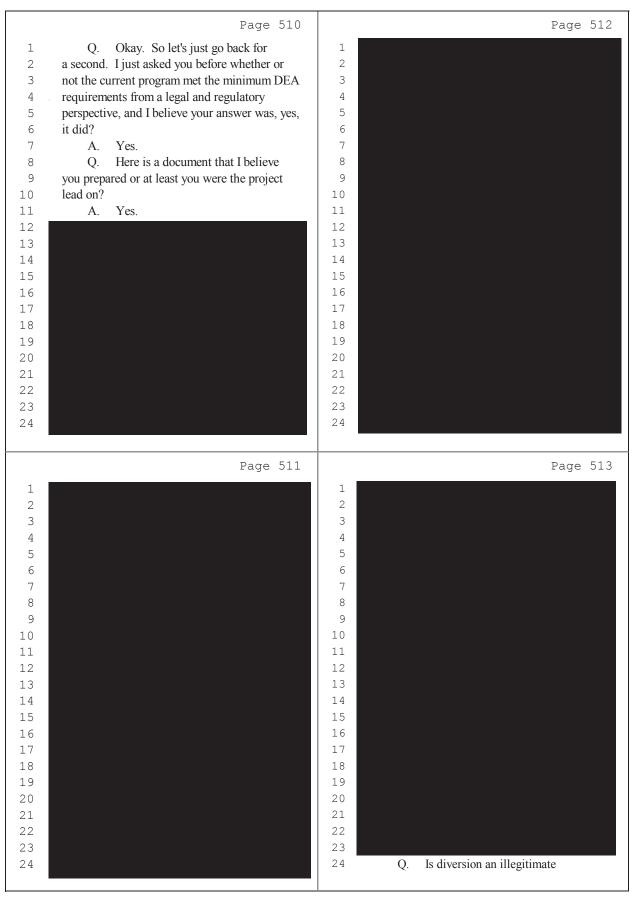
2 THE	VANNI: Object to form.	1	Break Break Control Co
2 THE 3 suggestion		1 +	BY MR. BUCHANAN:
3 suggestio	WITNESS: They were my	2	Q. Is this being presented in
	ns for improvement.	3	November of 2014?
		4	A. It is what I presented.
	act, these were items that	5	Q. Okay.
	der a risk assessment of 25, 25,	6	A. And it was presented as
7 the most sever		7	suggestions, and that's how I was asked to
8 A. Yes		8	present it as well.
	sk because you didn't have	9	Q. And what we have here are, look
•	s in place prior to November of	10	in the parking lot, right?
11 2013, right?	on proceeding to the control of	11	A. Again, all things that DEA said
	y're not required by DEA.	12	during conferences as suggestions for companies.
	a matter of whether they're	13	Q. These are your words, right?
14 required, ma'a		14	A. Yes.
15 A. It is		15	MS. VANNI: Object to form.
	statute, the statute states	16	THE WITNESS: Suggestions, yes.
~	tain effective controls against	17	BY MR. BUCHANAN:
18 diversion, corr		18	Q. These are your words, correct?
· · · · · · · · · · · · · · · · · · ·	l we did, yes.	19	MS. VANNI: Object to form.
		20	THE WITNESS: This is my guidance
	answer my question.	21	to industry for suggestions of things
		22	that they can look at to add to what's
ζ	t's what the statute says?	23	•
23 A. Yes		24	required by the regulation. BY MR. BUCHANAN:
Q. Not	and we did?	24	DI MR. BUCHANAN.
	Page 491		Page 493
1 A. And	we did.	1	Q. So let's look at this one.
2 MS. V	ANNI: Objection.	2	"Observe parking lot for suspicious activity,
3 BY MR. BUCH	ANAN:	3	license plates from multiple states, long lines,
4 Q. That's	s not the question. The	4	security guards, etc.," right?
	must maintain effective	5	A. Yes.
	diversion, correct?	6	Q. If pharmacy, are most controlled
_	OSKI: Object to form.	7	product prescriptions written by a handful of
	WITNESS: Yes.	8	physicians? Same prescription? Same
9 BY MR. BUCH		9	combination? Do they follow up with physicians?
	re the DEA sat with you in	10	All reasonable things to do, right?
•	you, as the head of DEA	11	MS. VANNI: Object to form.
	oversight of SOM by early 2013,	12	THE WITNESS: All good
-	umber of things the company	13	suggestions, yes.
	revamp its SOM, correct?	14	BY MR. BUCHANAN:
	ANNI: Object to form.	15	Q. All things that you thought
	WITNESS: I had outlined a	16	worthy to highlight in your presentation about
	things I wanted to improve.	17	this topic for a robust suspicious order
18 BY MR. BUCH		18	monitoring system in November of 2014, correct?
	enough. And what you did	19	MS. VANNI: Object to form.
,	you went out and told industry,	20	THE WITNESS: Ways to enhance the
-	rs, others, these are the	21	•
*		22	program, yes. MR. BUCHANAN: I think I'm off,
	effective program, correct?	23	
	ANNI: Object to form.		so with that, let me just check with my
24 THE V	WITNESS: No. These are	24	colleagues. I've gone over my allotted

Page 494 Page 496 1 1 time, ma'am. I would have loved to have 2 2 spent more time with you. 3 THE WITNESS: I'm sure. 3 Q. Okay. And your title changed 4 MR. BUCHANAN: Maybe we'll have a 4 from director to vice president? 5 chance to talk further. Thank you very 5 A. Correct. 6 6 Were your job duties essentially 7 THE VIDEOGRAPHER: Going off the 7 the same at both Qualitest and HD Smith, or was 8 record, 5:03 p m. 8 there some distinction? 9 9 A. There were definite differences (Brief recess.) 10 THE VIDEOGRAPHER: We're now 10 since it was a manufacturer versus a wholesaler. 11 going back on the record. The time is 11 O. You testified earlier with regard 12 12 to Exhibit Number 2, which is the summary of the 5:39 p m. 13 13 BY MR. YOUNG: suspicious order monitoring experience that I 14 think you prepared, I think you testified 14 Q. Hi, Ms. Norton. My names is 15 James Young, and I'll try to speak quickly since 15 earlier that some of the representations in here we only have 45 minutes, though intelligibly. 16 were slightly embellished or not exactly 16 17 17 accurate because you were trying to get the job I'm going to talk to you about 18 18 at HD Smith. your experience at HD Smith. So and you have 19 different counsel with you now, who is actually 19 Do you recall that testimony? 20 20 representing HD Smith, Mr. Leeder. MR. LEEDER: Object to form. 21 21 A. Yes. THE WITNESS: Yes, I do recall 22 So at some point in time, you 22 that testimony. 23 went to work for HD Smith, I take it? 23 BY MR. YOUNG: 24 24 Yes, I did. Q. And do you know of the top of Page 495 Page 497 1 Do you recall the date that you 1 your head which portions or provisions of this began employment there? 2 2 summary in Exhibit 2 were -- are not completely 3 2014 through 2016. 3 accurate? How is it that you came to be 4 4 MR. LEEDER: Can you provide her employed at HD Smith? Did you answer an ad, 5 5 a copy. 6 were you recruited, did you talk to somebody 6 THE WITNESS: Yeah, not without 7 7 about a job? reviewing. 8 A. I believe I got a call from a MR. YOUNG: It's Exhibit 2. It 9 recruiter and applied, was interested in 9 wasn't my exhibit. 10 10 Illinois. My husband worked for AbbVie, and MR. LEEDER: Here, I can share 11 they had a facility in Illinois, so was looking 11 it. 12 to kind of have two of us in one place for a 12 MR. YOUNG: I just happen to have 13 13 change and also for the promotion. this. 14 Q. And I wanted to ask you about 14 BY MR. YOUNG: 15 that. You mentioned on your earlier testimony 15 So and I guess I'll direct your that it was actually a promotion from your attention to a couple specific things. On the 16 16 17 current job at Qualitest. 17 Qualitest section which begins, in my version at 18 Do you mean that in title or in 18 least, on page 2, there is reference in here to 19 19 salary or both? using sales and chargeback data, it's in the 20 20 second full paragraph, in the middle. It says, 21 21 "Sales and chargeback data are both used," and I 22 22 think on earlier examination you hedged a bit 23 23 and suggested that chargeback data may not have 24 24 been used during your tenure at Qualitest?

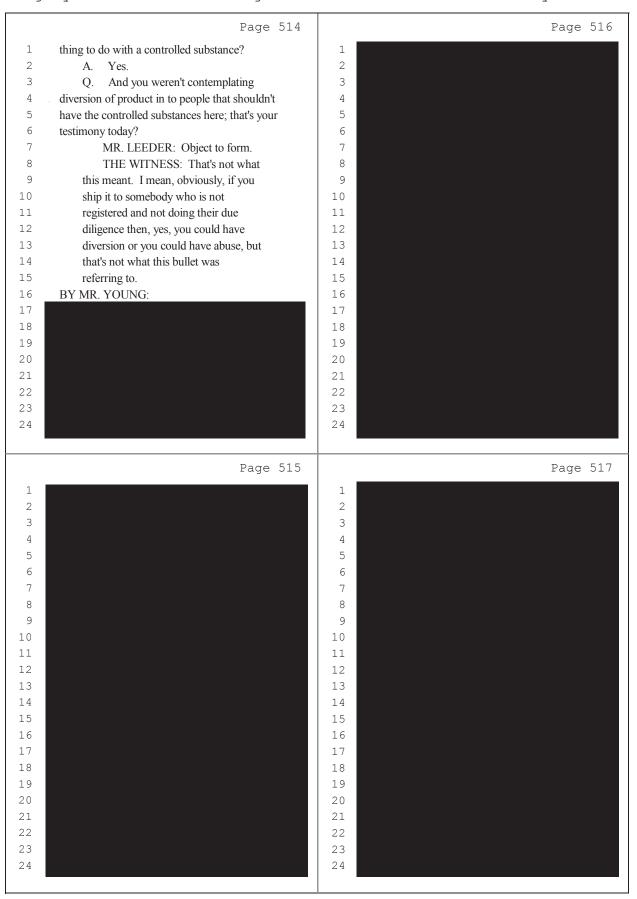
Page 500 Page 498 1 Huntsville/Madison County? 1 MR. LEEDER: Object to form. THE WITNESS: I know that we used 2 2 A. I was actually contacted by them. 3 -- we did look into sale -- to 3 They were really looking for a donation from chargeback data. I don't recall when it 4 Qualitest. That was their initial goal. They 4 5 were calling all local companies and asking for 5 was actually implemented, if it was 6 implemented before I left or if it was donations, and the woman asked me if I would 6 7 implemented after I left. I don't 7 like to attend one of their meetings, and I did 8 recall exactly. I know there were 8 and found it to be very informative. Local 9 9 struggles with getting the data and police officers were presenting on things they 10 getting it in a format that we could 10 were seeing in the community, and, basically, 11 11 that's how I got into the group. use. 12 Q. And so you put it to this 12 BY MR. YOUNG: 13 13 This document was prepared while document that you gained diversion information you were still employed at Qualitest, correct? 14 14 through your -- both your NADDI/DEA conferences 15 15 and through this position as a board member. A. What type of information were you exposed to as 16 16 O. And the specific language is sales and chargeback data are both used, 17 a board member of that organization, diversion 17 18 specific information? 18 correct? 19 A. I mean, more just things that 19 A. Yes. 20 20 And that would suggest to me were being abused or seen in the area, in the 21 that, in fact, both sales and chargeback data 21 very local area, because it was a township 22 are used at Qualitest? 22 organization, so just things that the local 23 Agreed. 23 police and the narcotics task force were seeing Okay. But is it your reflection 24 24 Q. being abused or diverted, so marijuana even they Page 499 Page 501 1 and recollection today that either sales or 1 talked about, some of the things that they were 2 chargeback data was not used by Qualitest during 2 seeing that were more gang related, that type of 3 your tenure there? 3 thing. 4 MS. VANNI: Objection to form. 4 Do you recall whether any of the 5 THE WITNESS: I wouldn't have 5 items that were being diverted were the items 6 lied about that in this document, so it 6 that Qualitest manufactured or distributed at 7 7 must have been in use before I left, but that time, for example, Vicodin? 8 8 A. I think that there was mention of I didn't recall it being used at the 9 time. I thought -- I thought that it 9 those products, not necessarily the Qualitest 10 was still under research when I left for 10 brand, but those products generally. 11 some reason, I had that in my head. 11 Q. Did you ever take any information 12 BY MR. YOUNG: 12 from that organization and go back to Qualitest 13 Q. Okay. There's also reference in 13 and investigate or research whether or not there 14 the first full paragraph, the very last sentence 14 were issues relating to diversion of Qualitest 15 15 under Qualitest, it says that you gained products? 16 additional diversion information through 16 MS. VANNI: Object to form. 17 conferences and through your position as a board 17 THE WITNESS: I presented that 18 member for the Partnership for a Drug Free 18 information, some of the information 19 Community in Huntsville/Madison County. I'm 19 that I received at some of our 20 sorry. It's not the last sentence, it's the 20 operations leadership team meetings. I 21 second to last sentence. 21 think one meeting, maybe two I presented 22 22 at, but I wasn't going back and looking Yes, that's correct. 23 What led you to join the board of 23 for diversion because we didn't have --24 the Partnership for Drug Free Community in 24 I didn't see any gap that this could



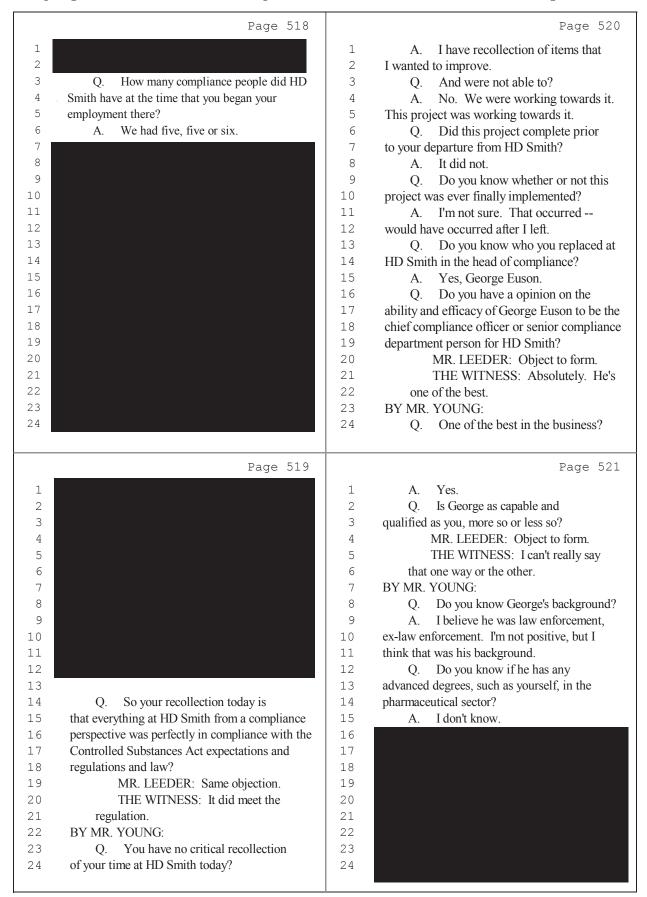
Page 506 Page 508 Q. Were you critical of HD Smith's 1 1 system in place was compliant with the CSA? 2 2 Yes, that's correct. compliance program during your tenure at HD A. 3 Smith? 3 O. And if that system continued 4 MR. LEEDER: Object to form. 4 without any changes or modifications that 5 THE WITNESS: I would not say 5 wouldn't be an issue from a legal or regulatory 6 6 basis, correct? that I was critical so much as, again, I 7 was looking for improvements to the 7 MR. LEEDER: Object to form. 8 8 program, as with anyplace that I go and, THE WITNESS: Not from a legal or 9 9 regulatory basis, I didn't believe that you know, handle compliance. So there 10 were improvements that I wanted to make, 10 was the case. 11 11 BY MR. BUCHANAN: ves. 12 BY MR. YOUNG: 12 Okay. Did you engage in a 13 13 Q. How about specifically with project to evaluate and improve the -- what's 14 14 called the CSOMP program, the SOMS program? regard to the suspicious order monitoring system 15 or program that HD Smith had in place, when you 15 Absolutely, yes, I did. 16 16 first began your employment with HD Smith, what Okay. I'm going to show you I 17 17 was your opinion or assessment of their SOMS think we're on Exhibit 28, and it is going to be 18 program? 18 my internal Exhibit 12. Put a label on it here 19 When I first came on, I was very 19 for you. 20 20 impressed with the level of knowledge that the (Document marked for 21 employees had with their backgrounds, the ones 21 identification as Par-Norton Deposition Exhibit No. 28.) 22 that were, you know, people that were 22 23 investigating the orders and that were out in 23 BY MR. YOUNG: 24 24 the field. I also thought that there were very Q. That's called or it's captioned a Page 507 Page 509 1 1 good tools that we had available to us. We had "Project Initiation Form." 2 2 dispensing data that was scrubbed from patient Does that look familiar to you? 3 information -- of patient information removed, 3 A. Yes, it does. 4 and we had people that were really good from an 4 Q. And it has a date on it revised 5 IT perspective that were able to put that data 5 June 30th, 2015. 6 6 in a fashion that was really usable. Do you see that? 7 7 A. Yes. The system that was in place for 8 suspicious order monitoring on your first day, 8 Q. Okay. What do you recall about 9 this particular document, Project Initiation 9 did you ever make a determination as to whether 10 10 or not that system was in compliance or out of Form? 11 11 compliance with the legal and regulatory A. This was the form that was used 12 12 requirements of the Controlled Substances Act? to start an IT project at the company, so these 13 MR. LEEDER: Objection to form. 13 were things that I wanted to add to our program 14 14 to enhance it, and these were -- it's detailed 15 15 on here. 16 16 Q. Okay. In the middle of this 17 17 first page, there is a section that says "Impact 18 18 if project not performed," and there's some 19 19 numbered items underneath there. 20 Can you read for me what number 1 20 21 21 is under impact? 22 22 23 23 Okay. So your opinion at the 24 time that you began with HD Smith was that the 24

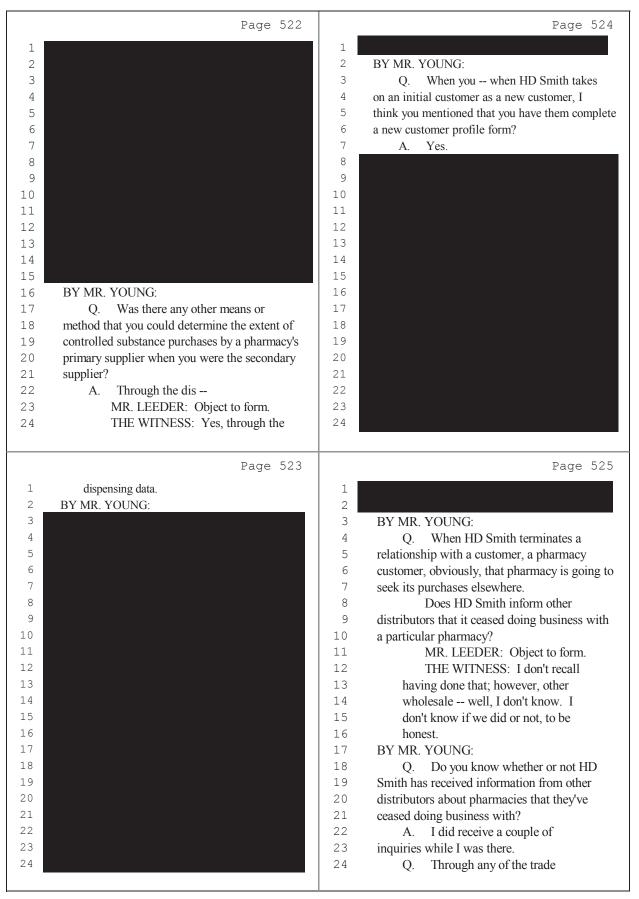


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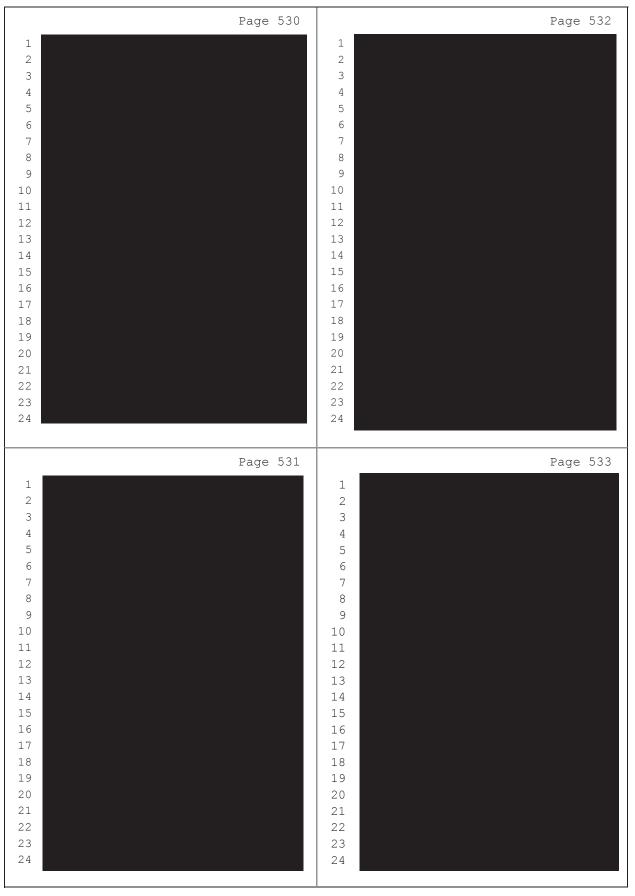
130 (Pages 514 to 517)



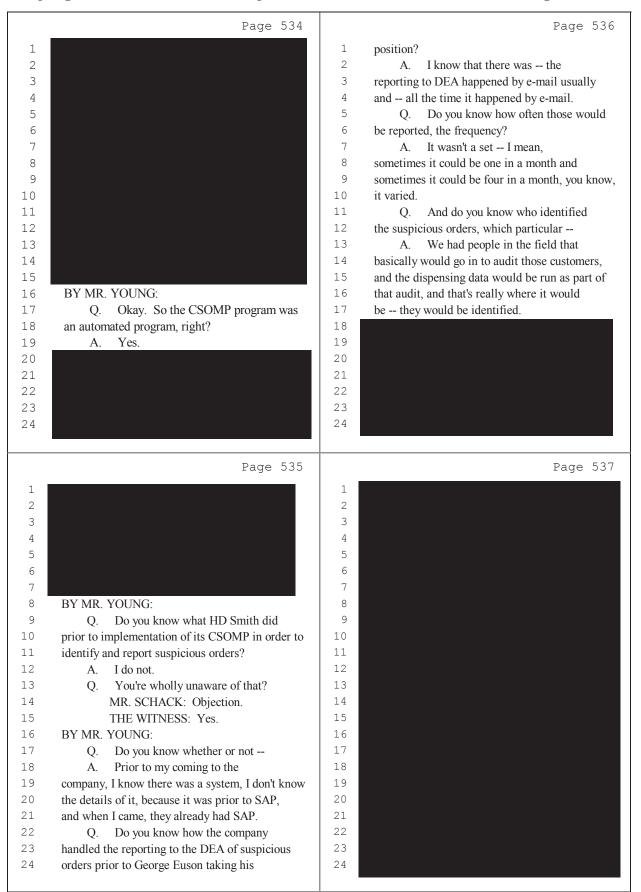


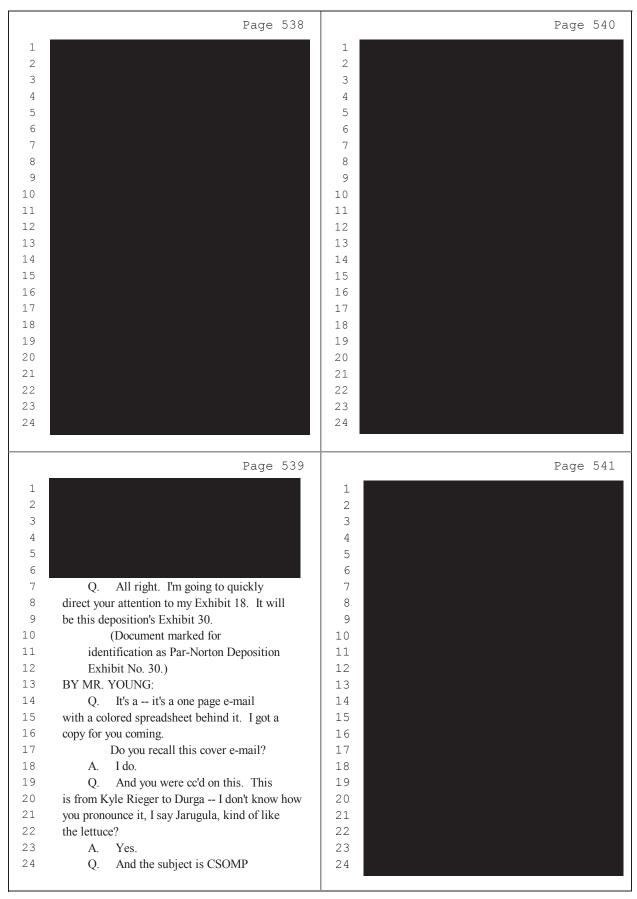
132 (Pages 522 to 525)

Page 526 Page 528 1 1 associations or working groups or Listservs or department conduct investigations in order to any of the other various pharmaceutical 2 2 determine whether or not -- or I should say 3 distributor or wholesaler organizations, do you 3 conduct analysis or investigations in order to know whether or not such information is shared 4 4 determine whether or not the establishment of 5 among distributors of bad actor pharmacies or 5 the initial URLs were sufficient to identify 6 suspicious pharmacies? 6 suspicious orders? 7 A. No, I mean, that would be 7 MR. LEEDER: Objection. 8 competitive information, so they wouldn't share 8 THE WITNESS: Yes, they were 9 9 conducting analysis on a daily basis. 10 Q. Do you know whether or not the 10 They were constantly looking at 11 DEA or any state board of pharmacy has ever 11 customers and numbers. shared with you information about suspicious MR. YOUNG: I want to show you --12 12 this is going to be number 14 in your 13 pharmacies that it was investigating or that it 13 14 had concerns about? 14 book. It's going to Exhibit 29. I do 15 MR. LEEDER: Object to form. 15 have copies for you guys. I'm sorry. THE WITNESS: Not on their own. 16 16 Just trying to get this done as quick as 17 If we conveyed to DEA that we were 17 possible. 18 18 looking at a particular pharmacy or if (Document marked for we reported that pharmacy to DEA, they identification as Par-Norton Deposition 19 19 20 have on occasion made comment about 20 Exhibit No. 29.) 21 looking into that particular customer as 21 BY MR. YOUNG: 22 well. It was infrequent because it's 22 Q. This is captioned "Meeting 23 not like DEA to share that information, 23 Minutes." 24 but the people that I had working for me 24 Do you recognize this document? Page 527 Page 529 1 1 had -- some of them, a couple of them MR. LEEDER: I just want to note 2 2 had very good working relationships with for the record that this is after her 3 DEA. 3 departure from the company. 4 BY MR. YOUNG: 4 BY MR. YOUNG: 5 5 Q. Have you ever seen this document, 6 6 though? 7 7 A. No. I've seen the template used 8 8 previously, but I haven't seen this. 9 9 Q. Okay. I just want to walk 10 10 through this document with you to see -- get 11 11 your reflection on some of the information in here. Can we go to page 2, under Number 9 under 12 12 13 13 the Agreement, section E, "customers with less." 14 joined HD Smith, based on your prior experience 14 MR. SCHACK: Can you identify it 15 for the record with a Bates number on 15 in the industry or your prior education and 16 16 training, about the particular way in which HD there. 17 Smith established its URLs for new customers? 17 MR. YOUNG: Oh, I just handed you 18 MR. SCHACK: Objection. 18 -- oh, I'm sorry. I just handed it to him. Yeah, the Bates range is -- boy, 19 THE WITNESS: No I thought the 19 20 information was -- was pretty well 20 if I could read that. 21 orchestrated as far as that goes. 21 MR. LEEDER: It's 294884 through 22 BY MR. YOUNG: 22 294886. 23 23 Q. Did you ever either yourself or BY MR. YOUNG: 24 have your -- the folks in your compliance 24 Q. And it says in Number 9,

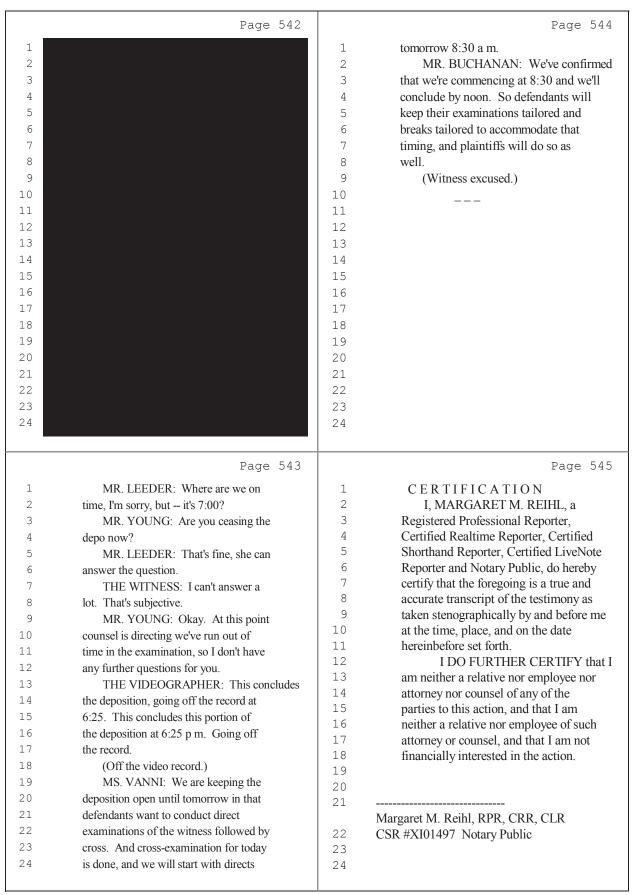


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136 (Pages 538 to 541)



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Highly Confidential - Subject to Further Confidentiality Review

	Page 546
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2	ERRATA
3	PAGE LINE CHANGE
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6	REASON:
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2.4	REASON:
	Page 547
1 2	ACKNOWLEDGMENT OF DEPONENT
3	I, TRACEY L. NORTON, do hereby
4 5	certify that I have read the foregoing pages, and that the same is a correct
6	transcription of the answers given by me
7 8	to the questions therein propounded, except for the corrections or changes in
9	form or substance, if any, noted in the
0	attached Errata Sheet.
2	
3	
	TRACEY L. NORTON DATE
j	Subscribed and sworn to before me this
)	day of, 2018.
	My commission expires:
9	Notary Public
0	
1 2	
3	
24	

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